Message

From: InsideEPA.com [insideepa-alerts@iwpnews.com]
Sent: 5/18/2018 10:53:50 AM
To: Jackson, Ryan [jackson.ryan@epa.gov]
Subject: The Morning Headlines from InsideEPA.com -- May 18, 2018

REDEFINING EPA: Overhauling an agency and its mission -- Complete coverage

May 18, 2018

The Weekly Focus

Absent Federal Policy, Governments File Tort Suits For Environmental Harms

From fossil fuels that cause climate change, to lead paint and a host of toxic chemicals, state, county and city governments are increasingly turning to common law nuisance claims to recover cleanup and other funds from manufacturers, a growing sign that federal policy may be inadequate -- or at least insufficiently funded -- to address these harms.

Latest News

Inhofe Floats 'Legislative Fix' To Codify Limits On States' CWA 401 Decisions

Sen. James Inhofe (R-OK) is suggesting Congress create "a good legislative fix" to prevent states from using their authority under Clean Water Act (CWA) section 401 to stall federal projects such as construction of natural gas pipelines, drawing support from Assistant Secretary of the Army for Civil Works R.D. James at a May 17 hearing.

EPA Proposes To Scrap Most Obama-Era Revisions To RMP Program

The Trump administration is proposing to scrap most requirements of the Obama-era final rule updating EPA's facility accident prevention program, rescinding numerous new safety requirements in response to industry and state petitions, and arguing that EPA failed to adequately coordinate with other agencies in issuing the costly changes.

EPA Again Finds Formaldehyde Poses Leukemia Risks But Stalls Study

After years of additional study and scientific review, EPA has again found that formaldehyde poses leukemia and other cancer risks, though Democratic senators say the draft finding has prompted Trump EPA appointees to block release of the assessment and they are urging Administrator Scott Pruitt to quickly release it.

Democrats Take Rare Step Of Using CRA To Kill Trump Rule, Despite Critique

Democrats are taking the rare step of using the Congressional Review Act (CRA), the law that eases Congress' ability to repeal EPA and other agencies' rules, to block a Trump administration rule rolling back Obama-era 'net neutrality' mandates, despite criticism from environmentalists that it legitimizes use of a poorly-written law that Republicans and industry have long-used as a deregulatory tool and which they are seeking to repeal.

Daily Feed

Narrow CWA test fails to make the cut as Farm Bill amendment

While the House Rules Committee did not allow a floor vote on the proposed Farm Bill amendment, the language limiting which waters are regulated could still serve as a marker for EPA's upcoming rule.

EPA touts 'renewed emphasis' on self-audit policies

EPA is promoting "opportunities to increase compliance through use of existing self-disclosure policies or tailored programs."

Wehrum sidesteps queries on SAB review of science rule

The EPA air chief's responses to a Democratic lawmaker's questions suggest the agency may urge its science advisors to avoid a review of its controversial rule seeking to block the use of 'secret science.'

Ewire: Amid scandals, Pruitt lawyers up

In today's Ewire: The EPA chief has hired a white-collar defense attorney to advise him as he faces more than a dozen official investigations, and hired another attorney to set up a legal defense fund.

Wehrum strongly hints EPA will not scrap GHG risk finding

EPA's air chief said Administrator Scott Pruitt is trying to find a way to allow critics of the finding have "some voice," but he said there is no "process" to solicit those views and there is no "schedule" to do so.

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Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 5/18/2018 9:49:28 AM
To: Bolen, Brittany [bolen.brittany@epa.gov]
Subject: Morning Energy, presented by Chevron: Another House WOTUS vote ... maybe — Trump signs efficiency EO — More calls for release of chemical safety study

By Kelsey Tamborrino | 05/18/2018 05:43 AM EDT

With help from Anthony Adragna and Annie Snider

ANOTHER HOUSE WOTUS VOTE ... MAYBE: The House is scheduled to vote today on an amendment to the farm bill, H.R. 2 (115), from Indiana Republican Rep. Jim Banks that would repeal the Obama administration's Waters of the U.S. rule. Provisions targeting the rule, which is deeply reviled in farm country, have been approved repeatedly, including when attached to appropriations measures, only to be stripped in the end. But WOTUS opponents keep hoping that the stars will align for them on a must-pass bill.

Banks touted the amendment on a local radio show Thursday. "With the farm bill on the floor, I thought, 'Well, this is a natural place to fully and permanently repeal WOTUS once and for all," he said, adding that groups like Heritage Action, the U.S. Chamber of Commerce and Club for Growth, have backed his amendment. "This is a rule that scares not just farmers, but a lot of property owners and developers and people who understand that this is federal government going way too far," he added.

The farm bill may not be that measure, though — at least not right now. As Helena Bottemiller Evich, Liz Crampton and Rachael Bade report, the House Freedom Caucus is threatening to scuttle the bill unless a vote on conservative immigration legislation is held first. House GOP leaders maintain lawmakers will still vote on the legislation today, despite the threat.

Separately, 40 environmental groups — including the League of Conservation Voters, Earthjustice and the Sierra Club — signed onto a letter urging House lawmakers to reject the amendment. "It's really this simple: a vote for this rider is a vote against clean water, a vote to expose even more communities to unsafe drinking water, a vote to limit the scope of the Clean Water Act, and a vote to allow polluters to destroy our precious waterways," they write.

The House is scheduled to meet at 9 a.m. for legislative business, with first and last votes expected between 10:30 a.m. and 11:30 a.m. See the full list of amendments here.

GET A WRDA IN EDGEWISE: Meanwhile, the House Transportation Committee will release its own Water Resources Development Act today, the committee's chairman said. The bill is expected to differ significantly from the Senate's version that will be marked up Tuesday, Pro's Annie Snider and Anthony Adragna report, but it does have the support of the committee's ranking member Peter DeFazio and the top Democrat and Republican on the Water Resources and Environment Subcommittee. GOP Rep. Garret Graves, the subcommittee chairman, said the House measure will include language relating to one of his top priorities: moving the Army Corps of Engineers out of the Defense Department. On the Senate side, both Democrats and Republicans have been wary of that idea. However, Graves indicated the House bill will not make that move immediate.

WE MADE IT TO FRIDAY! I'm your host Kelsey Tamborrino. Turns out there are a few different ways to answer yesterday's trivia question. But I'm giving the win to LCV's Gene Karpinski, who was the first to identify Rock Creek Park, authorized in 1890, as what the National Park Service calls the third national park to

be designated by the federal government. For today, a related question: William Henry Jackson was the first person to photograph Yellowstone. What monument is home to the largest single holding of his paintings? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy, and @POLITICOPro.

TRUMP SIGNS EFFICIENCY EO : President Donald Trump signed an executive order late Thursday to prioritize efficiency in the government. The order calls on agencies to "prioritize actions that reduce waste, cut costs, enhance the resilience of Federal infrastructure and operations, and enable more effective accomplishment of its mission." It focuses on increasing efficiency of federal buildings and vehicles in a cost-effective manner. The president also directed the Council on Environmental Quality and the Office of Management and Budget to streamline energy and environmental requirements, in a simplified and accountable manner. Last year, the White House said, agencies spent more than $6 billion on energy for buildings and $635 million on water. Within 90 days, the Agriculture and Energy secretaries and the administrators of EPA and General Services, are tasked with reviewing relevant established government-wide guidance and in conjunction with CEQ, must "develop a plan and proposed timeline to modify, replace, or rescind such guidance, as necessary."

But the order also notably rescinds an Obama-era order from March 2015 that focused on sustainability, requiring agencies to slash its greenhouse gas emissions and address climate change. That EO set a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years. Trump's order makes no mention of climate change or emissions reductions. Instead it calls on agencies to track and report greenhouse gas emissions. Read the order here.

SENATE'S 'BIG FOUR' ON NUCLEAR WASTE PLAN MEETING: A bipartisan group of four senior senators are planning to get together in hopes of launching a new push on nuclear waste legislation, according to Sens. Lisa Murkowski and Lamar Alexander. "Our staffs have been working, but I don't know if a date has been set," Murkowski, chairman of the Energy Committee, told ME. Their Democratic counterparts at the meeting would be Sens. Dianne Feinstein and Maria Cantwell. The planned meeting comes after the House passed its own broad nuclear waste overhaul that would move the Yucca Mountain repository forward.

SIMPSON STILL 'LEANING NO' ON RESCISSIONS: Rep. Mike Simpson, who chairs an Appropriations panel responsible for DOE funding, says he's "leaning no" on a proposed list of $15.4 billion in cutbacks from the administration but plans to continue his review of it. "I want to look at the loan guarantees," he told reporters. "Most of them are probably going to be OK. There some that might not be." Remember Simpson's one of several senior Appropriators who've expressed reservations about the package.

BARRASSO STILL CONCERNED ABOUT PRUITT: Senate EPW Chairman John Barrasso says he isn't giving EPA Administrator Scott Pruitt a free pass even as he remains non-committal about when he'll haul the embattled EPA chief before his committee. "I still have lots of concerns with regards to spending issues," he told reporters. "I continue to send and ask questions."

ALL IN THE TIMING: Depending on when Pruitt created his legal defense fund, onlookers may have to wait another year to see who donated. As E&E News reports, the embattled EPA chief is required to report gifts received on his public financial disclosure report, which would include contributions to the legal defense fund established for his benefit, according to guidance on the Office of Government Ethics' website. But those reports are only filed once a year, meaning if Pruitt's defense fund was created this year, he'd report it for the 2018 calendar year, which isn't required to be filed until May 2019 at the earliest. Of course, that means if Pruitt created the fund in the 2017 calendar year, it would be in the financial disclosure report that Pruitt recently got an extension to file. Read more.

BRIDENSTINE: 'GREENHOUSE GAS IS WARMING THE PLANET': NASA's Jim Bridenstine held his first town hall as administrator Thursday, where he clarified his stance on climate change. He said his position

on the issue has "evolved," and he described the impact of tornadoes in his home state. "I don't deny the consensus that the climate is changing, in fact I fully believe and know that the climate is changing," Bridenstine said. "I also know that we human beings are contributing to it in a major way." The former Oklahoma lawmaker, who was recently confirmed to the agency, faced previous criticism from Democrats over his denial that climate change is caused by humans. During Thursday's address, Bridenstine instead praised the work of NASA and defined carbon dioxide as a greenhouse gas. "We're putting it to the atmosphere in volumes that we haven't seen and that greenhouse gas is warming the planet," he said. "That is absolutely happening and we are responsible for it." Watch his remarks here.

MORE CALLS FOR RELEASE OF CHEMICAL SAFETY STUDY: Calls continue to mount for the Trump administration to release a hot-button assessment of the chemicals PFOA and PFOS that POLITICO reported Monday was described as a "public relations nightmare" by a White House official. New York Democratic Rep. Sean Patrick Maloney will add his voice to the chorus with a letter to Pruitt today. Maloney's Hudson River Valley district includes Newburgh, N.Y., where the chemicals have leached from the nearby Stewart Air National Guard Base. State-funded blood tests have found that residents there have more than three times the amount of PFOS in their blood than the average American.

HOUSE APPROPRIATIONS SCIENCE BILL ADVANCES: The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill Thursday on a party-line vote of 32-19. The fiscal 2019 measure would increase spending for federal law enforcement, NASA and the National Science Foundation by $2.9 billion to a total of $62.5 billion, Pro's Hugh Ferguson and Sarah Ferris report. NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request. Among the 18 amendments offered, two Democrat-offered NOAA-related ones were withdrawn. One was related to increasing funding for coastal resilience programs at NOAA, and another would increase funding for the NOAA climate research program.

Speaking of NOAA: The agency found April 2018 marked the 400th consecutive month with temperatures above average. Additionally, NOAA said the average global temperature for April was 1.49 degrees F above the 20th-century average of 56.7 degrees — the third highest for April in the 139-year record, with 9 out of the 10 warmest Aprils occurring since 2005.

CLIMATE CAUCUS WELCOMES FIVE MEMBERS: The Climate Solutions Caucus welcomed five new members to its ranks on Thursday: Reps. Erik Philip Paulsen, Tom MacArthur, Eliot Engel, Peter Roskam and Ron Kind. The additions bring the bipartisan caucus' total to 78 members.

CORPS GRID RESTORATION ENDS TODAY: At the direction of the CEO of the Puerto Rican power company PREPA and the Energy Unified Command Group, FEMA said that as of today the Army Corps of Engineers will no longer provide line restoration work for the power authority. Instead, PREPA will oversee its contractors and the remaining work in grid restoration. PREPA reports 98.86 percent of pre-storm customers have had their power restored, with 16,723 remaining without power, as of Wednesday.

But FEMA said Thursday it had approved the extension of an Army Corps mission assignment that allows for the lease, generation and maintenance of three "mega generators" until PREPA completes its purchase of the generators.

NATURAL GAS AND NATO: Although it was not immediately clear how, Trump said Thursday gas would play a role in upcoming NATO talks. The president remarked on Germany's relationship with Russia during his meeting with Secretary-General Jens Stoltenberg, who praised Trump for pushing countries in the alliance to boost their defense spending. In his remarks, Trump specifically called out Germany for its "longstanding shortfall in defense contributions." Trump called the member nation "a very big beneficiary" that "must demonstrate leadership." He added, "they're buying massive amounts of gas from Russia and paying billions

and billions of dollars. So I think that's something we'll be discussing later and we'll be discussing that at our meeting, and probably long before the meeting." The leaders' meeting came ahead of a NATO summit in July.

Meanwhile, The Wall Street Journal reported on Thursday that U.S. and European officials said Trump told German Chancellor Angela Merkel in April that Germany should drop support for Nord Stream 2, an offshore pipeline that would bring gas directly from Russia via the Baltic Sea. This would be in exchange for the U.S. starting talks with the European Union on a new trade deal.

DEPARTMENT OF CORRECTIONS: The New York Times set the record straight last night, issuing a correction to its story from April 13 that said the former head of Pruitt's security detail, Pasquale "Nino" Perrotta, had met for drinks with an an official from the EPA inspector general's office. That report had raised concerns in some quarters about the independence of the IG investigator.

The story, the paper said, "erroneously included Mr. Perrotta among those who gathered for beers at an event at the Elephant and Castle in Washington that was attended by Patrick Sullivan, the assistant inspector general who oversees investigations at the E.P.A. Mr. Sullivan said that Mr. Perrotta had been invited but did not attend that gathering and that he has never met for drinks with Mr. Perrotta, though he acknowledged that the two men met for lunch several months later at another restaurant near the E.P.A. headquarters."

MAIL CALL! Democratic Sens. Ed Markey, Sheldon Whitehouse and Tom Carper , members of the EPW Committee, called on EPA to publicly release a health assessment on the effects of formaldehyde exposure. They cite an exchange between Markey and Pruitt during his January appearance before the committee where Pruitt said he'd get back to the senator on the progress of the report. "Unfortunately, it appears that the agency may be succumbing to pressure from industry in its attempt to delay or block the publication of the formaldehyde health assessment," they write. Read it here.

CONGRATS ARE IN ORDER: Barrasso congratulated Wyoming Gov. Matt Mead in a letter this week on the dedication of the state's Integrated Test Center near Gillette. The carbon capture research facility, dedicated Wednesday, is a testing space off the back of the operating coal power plant. Five Carbon XPrize finalists — U.S., Canada, India, China and Scotland — will head to the site to put their concepts to capture CO2 from the power plant and convert it to a marketable product to the test. In his letter, Barrasso called the ITC "an important resource for Wyoming's economy." Read it here.

ROCKET TO THE SUN: House Science Chairman Lamar Smith said Thursday he submitted the names of committee members and staff to be placed aboard the Parker Solar Probe on its "mission to touch the Sun." NASA opened up the opportunity to the public to submit names to be stored on a memory card and installed on the probe before it launches this summer. "When I came across NASA's unique offer, I thought this would be a perfect and light-hearted opportunity to carve the names of the members and staff in history," Smith said in a statement.

SEE IT: Electricity generation will vary widely over the coming decades, according to U.S. Energy Information Administration's projections. Pro's DataPoint team breaks down the numbers in a graphic here. Want to add DataPoint to your Pro account? Learn more.

QUICK HITS

— Florida congressional delegation gives thumbs-down to offshore drilling, McClatchy.

— Republican lawmaker: Rocks tumbling into ocean causing sea level rise, E&E News.

— Emails show Interior expected to learn nothing from public input on Bears Ears review, Huffington Post.

— Zinke moves to protect critical minerals from foreign threats, Washington Examiner.

— Zinke tells greens he'll make 'grand pivot' to conservation, E&E News.

— Will Trump's pick to run EPA in California show up for work? Los Angeles Times.

HAPPENING TODAY

9:00 a.m. — House Energy and Commerce Environment Subcommittee hearing on various bills, 2123 Rayburn

9:30 a.m. — House Judiciary Regulatory Reform, Commercial and Antitrust Law Subcommittee hearing on "No Oil Producing and Exporting Cartels Act," 2141 Rayburn

12:00 p.m. — The National Capital Area Chapter of the United States Association for Energy Economics presentation on "How less-than-efficient humans interact with energy markets," 618 H St NW

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To view online:
https://subscriber.politicopro.com/newsletters/morning-energy/2018/05/another-house-wotus-vote-maybe-222339

Stories from POLITICO Pro

GOP leaders, Freedom Caucus face off on farm bill, immigration Back

By Liz Crampton, Helena Bottemiller Evich and Rachael Bade | 05/17/2018 04:34 PM EDT

House GOP leaders are daring the Freedom Caucus to sink their prized partisan farm bill, pushing ahead with a Friday morning vote despite conservative threats to tank it.

Speaker Paul Ryan's team haggled late into the night Thursday with Freedom Caucus leaders. To win the far-right, leaders gave the group what it originally asked for: the promise of a vote on a conservative immigration bill — albeit not until June.

But the Freedom Caucus retorted that they want the immigration roll call now before the farm bill gets a vote. Some fear leadership will renege on that vow, as they have on the issue in the past.

After Ryan's team explained to the group late Thursday that they could not do immigration before the farm bill, the group of conservatives held a conference call to discuss what to do.

With the vote still scheduled for Friday morning, it is unclear where things stand. GOP leaders are waiting for word on whether the Freedom Caucus will deliver the final votes needed to push the bill over the finish line. President Donald Trump, meanwhile, tweeted about the matter, asserting pressure on the right to get in line.

"Tomorrow, the House will vote on a strong Farm Bill, which includes work requirements," Trump wrote, referring to a new mandate in the bill requiring those receiving food stamps to find employment. "We must support our Nation's great farmers!"

Tensions over the farm bill escalated Thursday afternoon when Freedom Caucus Chairman Mark Meadows announced that his three-dozen members would not support the measure. In return for their vote, the North Carolinian said they'd need a vote on a bill crafted by Judiciary Chairman Bob Goodlatte that extends Dreamers' legal status for a host of conservative immigration policies.

"At this point there is no deal to be made," Meadows said exiting an hour-long Freedom Caucus powwow. "The vast majority of our members believe we should have a vote on immigration before the farm bill."

He added: "At this point there's not enough votes to pass the farm bill."

Even after the group rejected that offer, House Majority Leader Kevin McCarthy maintained that he was not pulling the bill from the floor. Senior Republicans are holding out hope that they could reach some sort of accord by Friday.

The scheme by conservatives could throw at least a temporary wrench in Ryan's welfare overhaul push. The farm bill, which covers agriculture subsidies, conservation, rural development and nutrition, would impose stricter work requirements on between 5 million and 7 million food-stamp recipients. The current farm bill expires Sept. 30.

With Democrats planning to vote against the farm bill because of the new work requirements, Republicans need the votes of the Freedom Caucus for the measure to pass.

The scramble to try to bring the bill to a vote this week highlights the deep divisions within the Republican Conference. On the right, conservatives have been lukewarm at best on the sweeping bill, arguing it both doesn't go far enough on work requirements for able-bodied adults receiving food stamps, and does nothing to rein in farm subsidies. Several Republican moderates, meanwhile, have quietly raised concerns about the work requirements.

Ryan has long been eyeing the bill as a rare chance to enact a piece of a welfare overhaul, a key priority for the outgoing speaker. It's the first farm bill cycle in decades where Republicans control both chambers of Congress and the White House.

Even if the leaders strike a deal with conservatives, the version of the bill is considered a nonstarter in the Senate. Senate Agriculture Chairman Pat Roberts (R-Kan.) and ranking member Debbie Stabenow (D-Mich.) are drafting a bipartisan bill. Roberts has said the Senate will not include work requirements, citing his need to get 60 votes.

The food stamp program, now formally known as the Supplemental Nutrition Assistance Program, helps more than 40 million low-income Americans buy groceries each month.

The program has long had bipartisan support as well as backing from large food companies and retailers, who now see SNAP as big business. But SNAP's rolls expanded greatly in the wake of the Great Recession, and while the numbers have come down somewhat, they have not returned to pre-recession levels.

While the farm bill has historically been passed by a coalition of urban and rural lawmakers from both sides of the aisle, talks between Republicans and Democrats broke down earlier this year in the House Agriculture Committee over the work requirements, making the process unusually bitter and partisan.

"The farm bill also keeps faith with these families by not only maintaining SNAP benefits but by offering SNAP beneficiaries a springboard out of poverty to a good paying job, and opportunity for a better way of life for themselves and their families," House Agriculture Chairman Mike Conaway (R-Texas) said when he unveiled the bill last month.

The bill would require adult SNAP recipients between the ages of 18 and 59 to work or be enrolled in a training program at least 20 hours per week. People who are disabled, pregnant or caring for a child under the age of 6 would be exempt. The plan would also expand the pool of money for state-run work training programs tenfold, from $90 million per year to $1 billion.

The plan to go along with a GOP-only farm bill was originally Ryan's, according to senior Republican sources. The bill is seen as a personal priority for the speaker, who will retire at the end of the year and has long eyed enacting comprehensive welfare reform.

With leadership relying only on Republican votes for the bill, the House Freedom Caucus saw their opportunity for leverage.

Meadows acknowledged that the farm bill is the last must-pass legislation before the federal government spending bill must be approved in October. "Obviously when you look at that it's a leverage point," he said.

Catherine Boudreau contributed to this report.

To view online click here.

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Shuster: House WRDA bill coming Friday Back

By Annie Snider and Anthony Adragna | 05/17/2018 03:14 PM EDT

The House Transportation and Infrastructure Committee will release its Water Resources Development Act Friday, Committee Chairman Bill Shuster said.

The measure has the support of the committee's ranking member, Rep. Peter DeFazio (D-Oreg.), as well as the top Democrat and Republican on the Water Resources and Environment Subcommittee, according to Rep. Garret Graves (R-La.), chairman of that subcommittee.

The House bill is expected to differ significantly from the upper chamber's measure. Graves said it will include language relating to one of his top priorities, moving the Army Corps of Engineers out of the Defense Department. Both Democrats and Republicans on the Senate Environment and Public Works Committee have been wary of that idea. However, Graves indicated the House bill will not call for an immediate move.

"There's a number of steps to the process in terms of how I think this will ultimately be done," Graves told POLITICO. "We do need to take a careful, constructive path forward because you don't want to come in and do something that's actually going to make it worse."

The Senate EPW Committee plans to mark up its bill next Tuesday, Committee Chairman John Barrasso (R-Wyo.) said today. He said he has not spoken with his House counterparts about their bill in the last couple of days and said the chambers are not coordinating their efforts.

WHAT'S NEXT: The House Transportation and Infrastructure Committee is expected to unveil its WRDA bill Friday. A markup could come as soon as next week.

To view online click here.

Back

Obama touts climate executive order: Back

By Andrew Restuccia | 03/19/2015 12:02 PM EDT

President Barack Obama said this morning that his administration is "leading by example" by requiring the government to slash its greenhouse gas emissions.

"This has been a team effort to make sure that we're doing everything we can to boost the energy efficiency of the federal government," Obama said during brief remarks at the Energy Department.

And he made the case that policymakers can deal with climate change, while also protecting the economy.

"We're proving that it's possible to grow our economy robustly, while at the same time doing the right thing for our environment and tackling climate change in a serious way," he said.

Obama signed an executive order this morning that sets a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years.

To view online click here.

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House clears nuclear waste bill that would move Yucca forward Back

By Anthony Adragna | 05/10/2018 11:27 AM EDT

The House today cleared nuclear waste legislation, H.R. 3053 (115), that would kick-start the stalled Yucca Mountain repository while also establishing an interim storage facility for spent nuclear waste.

Overcoming the strong objections of Nevada lawmakers, the bill passed 340-72, with bipartisan support. It would offer incentives to the state for allowing Yucca to advance, include federal land transfers associated with the site and change how user fees are collected to help build the repository, among other provisions.

"I think people are ready to do something rather than nothing," Rep. John Shimkus (R-Ill.), the bill's sponsor, told reporters earlier this week.

Key to getting the bill to the floor was breaking a monthslong "impasse" with House Appropriators on how to spend revenues collected through the Nuclear Waste Fund, an account containing tens of billions built on fees on nuclear-generated electricity. Shimkus said his compromise will allow lawmakers "be more honest brokers" going forward by walling off future collected fees from being spent on other programs.

Lawmakers rejected an amendment from long-time Yucca opponent Rep. Dina Titus (D-Nev.) concerning consent-based siting, while adopting other amendments requiring clearer annual reports on the Nuclear Waste Fund balance and a report on resources for communities dealing with nuclear waste issues.

WHAT'S NEXT: Shimkus said he doesn't expect to see the bill taken up in the Senate, where Yucca opponent Sen. Dean Heller (R-Nev.) faces a competitive reelection.

To view online click here.

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Some GOP appropriators resist Trump cutbacks Back

By Sarah Ferris and Kaitlyn Burton | 05/11/2018 05:03 AM EDT

Several GOP spending chiefs have cast doubt on President Donald Trump's proposed list of $15.4 billion in cutbacks, saying they're not yet ready to bury some of the targeted programs.

White House officials have pitched their rescissions package, H.R. 3 (115), as entirely noncontroversial, with some of the money sitting unused in accounts for two decades. Neutral experts have confirmed that the vast majority of the cutbacks would have zero programmatic effect.

But some longtime appropriators, including Senate Appropriations Chairman Richard Shelby (R-Ala.), are withholding support, even as most of their GOP colleagues flock behind Trump's first major attempt at deficit reduction to get a vote in Congress.

Some say they're skeptical of the administration's efforts to fast-track cuts to programs they aren't ready to kill, like rural infrastructure, clean energy and even a relatively new initiative that lets states use cash from unfinished earmarks projects.

"There's a lot of things there that don't make a lot of difference, but appropriators don't like rescissions, so we're going to have to think about that," Rep. John Carter (R-Texas), who oversees the Homeland Security bill, told POLITICO on Wednesday.

That initial resistance includes Sen. Lisa Murkowski — whose vote could help determine whether the bill passes the narrowly divided Senate. With Arizona Sen. John McCain's absence, Republicans have a 50 to 49 majority, and can't afford to lose a single GOP vote.

Murkowski (R-Alaska) said she isn't sold on the administration's proposal to cut $684 million from a clean energy loan guarantee program. "I want to make sure that if you take the funds from the account, you don't eliminate the program," the Interior-Environment Subcommittee chairwoman told reporters Thursday. "I don't want Title 17 programs eliminated. I want them reformed."

Rep. Mike Simpson (R-Idaho), who holds that position in the House, said Thursday he is "leaning no" on the proposal for the same reason. He said the clean energy program is "something I want to continue."

Shelby said he's concerned about cuts to the Appalachian Development Highway System. The White House has proposed $45.2 billion in cuts to that program, which the House matched in its bill unveiled Wednesday night.

"My state has benefited from that over the years," Shelby told reporters, noting that the bill could still see tweaks before it comes to a vote in the Senate. "I'm waiting to see what comes up first and where it comes up."

As a 24-year veteran of the Appropriations panel, Shelby is one of few sitting lawmakers to witness the last round of rescissions in 2000. And he said any cost-cutting proposal from 1600 Pennsylvania Avenue is likely to find at least a few critics on Capitol Hill.

"Since I've been up here — and I've been up here a few years — there's always some things in the rescissions package that a lot of members are committed to," Shelby said.

Meanwhile, Rep. Mario Diaz-Balart (R-Fla.) complained that the rescissions bill would roll back money that states could use for items such as infrastructure projects. That's because states can now access old cash that was earmarked for efforts that didn't get off the ground.

"Now, if you take it out, you're taking money out of the states' funds," the Transportation-HUD panel chairman said. "If you believe, like me, that infrastructure is a needed investment, I think that's problematic taking that away."

Appropriators are a fiercely independent breed on Capitol Hill, faced with a declining share of influence in the recent stop-and-go funding cycle. Now, they've been handed the largest-ever presidential rescissions request without a chance to vet it through their committees.

House GOP leaders are planning to bring the bill directly to the floor for a vote, as soon as next week. The Senate is expected to follow suit.

The Office of Management and Budget has said the $15.4 billion rescissions proposal would actually amount to less than $3 billion in spending cuts.

What's alarming to appropriators, though, is that the proposal would drain from Congress' ever-dwindling pool of "offsets," the equivalent of a rainy day fund for pending legislation.

The money that would be trimmed from the Children's Health Insurance Program, a federal fund for low-income families, for instance, has been used to help pay for the annual Labor-HHS-Education bill for years.

"Look, there's $5 billion of CHIP money that you can't spend. Why wouldn't you reclaim that money and put it back in the federal treasury?" asked Rep. Tom Cole, (R-Okla.), who oversees Labor-HHS-Education spending. "Or you can use it for an offset on something, which is normally what we've done in the past."

Cole is one of four appropriators to co-sponsor the package, along with Republican Reps. Tom Graves of Georgia, Kay Granger of Texas and Steve Womack of Arkansas. Of those, everyone but Womack is running for House Appropriations chairman this fall. And Womack is the leader of the House Budget Committee.

(The other contender for the House spending panel's gavel, Rep. Robert Aderholt (R-Ala.), was the first appropriator to go on record supporting the idea last month.)

"It's been carefully drawn, it doesn't violate our omnibus agreement, it doesn't violate our defense bill," Granger told POLITICO this week. Granger's panel oversees the Pentagon's budget, which wouldn't see a dollar cut under the White House's package.

Cole acknowledged that the dwindling pool of offsets would "probably" make it tougher for Congress to pay for some legislation down the road. But he said there are plenty of other ways to pay for something if leadership looked hard enough.

"In a $4 trillion budget, there's always something you can find to offset something else if it's really politically important enough to do," Cole said.

Anthony Adragna contributed to this report

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Democrats fear Pruitt's legal defense fund could create conflicts of interest Back

By Alex Guillén | 05/16/2018 04:38 PM EDT

EPA Administrator Scott Pruitt's newly formed legal defense fund has the embattled administrator's critics wondering whether companies he regulates will come to Pruitt's rescue behind the scenes.

Legal defense funds are subject to few formal rules, although any donations to help pay for Pruitt's lawyers would have to abide by existing ethics rules, including limitations on gifts from lobbyists or those with business before an official. While the Office of Government Ethics in September issued nonbinding guidance recommending that executive branch officials reject anonymous donations and consult with ethics officials before establishing such funds, critics say the system is ripe for potential abuse.

"You can see the conflicts," Sen. Tom Udall (D-N.M.) told reporters Wednesday, after pressing Pruitt on the legal defense fund during a congressional hearing. "A business is saying, 'I want this regulation to be repealed and so I'm going to give $100,000 to your legal defense fund.' That kind of activity just shouldn't be happening."

Experts say that even with those ethics boundaries, Pruitt will have significant leeway in deciding just how transparent the fund will be.

Craig Holman, a government affairs lobbyist at Public Citizen, compared the situation to the "Wild West."

"Legal defense funds in the executive branch can be set up any way the official prefers, including refusing to disclose the sources and amounts of donations," said Holman, who has petitioned OGE to create official rules for such funds.

In Pruitt's case, the fund must be set up as a private entity run by an independent third party and should not ask for donations from energy companies or lobbyists in order to comply with ethics laws, said Don Fox, a former general counsel and acting director for OGE. As for any other restrictions, he said, "OGE says, basically, 'We don't bless this; we're not telling you whether this good, bad or indifferent, but if you follow these guidelines, you should be OK.'"

Pruitt, who was an accomplished political fundraiser before joining the Trump administration, said the fund had been set up by his attorneys, not himself.

Pruitt told lawmakers on Wednesday that his attorney "who's done this for a number of years" has worked with the GAO "to make sure it's done properly."

He also said he would follow the advice of the White House Office of Legal Counsel on whether to accept anonymous donations, but he did promise not to personally solicit money from lobbyists or companies with business before EPA.

Asked by Sen. Chris Van Hollen (D-Md.) whether he would commit "not to accept donations from lobbyists or corporations that have business before the EPA," Pruitt replied, "Absolutely," although he then amended that statement.

"Let me clarify something. I don't accept the donations; I don't solicit donations. That's done by attorneys and others," Pruitt told the Maryland Democrat at Wednesday's hearing before a Senate Appropriations subcommittee. Pruitt said he would follow the advice of GAO and the White House regarding whether to accept anonymous donations.

As a rising star attorney general in Oklahoma several years ago, Pruitt raised millions for his own campaigns and outside conservative groups. Pruitt helped land millions of dollars in donations from the energy industry to the Republican Attorneys General Association, where he served several years as chair and an executive board member.

Major donors to RAGA during that time included Koch Industries and Devon Energy, an Oklahoma-based oil and gas company with close ties to Pruitt.

Pruitt later chaired the Rule of Law Defense Fund, but that group is not required to disclose its donors.

He also created a leadership PAC and a super PAC to promote his interests. Each one had raised about $45,000 but gave that money away and shut down once he was nominated to run EPA.

Pruitt did not specify which attorney set up his fund. The Washington Post on Wednesday reported it is run by Cleta Mitchell, an attorney at Foley & Lardner.

Mitchell did not answer questions from POLITICO about the fund.

"I do not respond to questions from reporters about any legal matters in which I may or may not be involved," Mitchell wrote in an email. "Administrator Pruitt has been a friend and client for a number of years."

Mitchell was a Democrat in Oklahoma's House of Representatives from 1976 to 1984, but her later law practice focused on representing conservatives, including Sen. Jim Inhofe (R-Okla.). She is a former board member of the National Rifle Association and the American Conservative Union, which runs the annual conservative confab known as "CPAC."

Mitchell has come to Pruitt's defense on Twitter in recent months.

On April 6, shortly after The New York Times reported that Pruitt had removed or reassigned career and political officials who questioned his actions, Mitchell tweeted: "NYT is outraged that Scott Pruitt moved EPA employees who fought his initiatives. That's exactly what we WANT him to do."

She tweeted a few days later that Sen. Sheldon Whitehouse (D-R.I.) "and his crazy environmentalist cronies have FED the hostility against Pruitt. Pray for Pruitt's safety."

Ben Lefebvre, Annie Snider and Anthony Adragna contributed to this report.

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How Trump's climate skeptics are changing the country Back

By Emily Holden | 03/07/2018 05:02 AM EDT

President Donald Trump is filling the upper ranks of his administration with appointees who share his disbelief in the scientific evidence for climate change — giving them an opportunity to impose their views on policies ranging from disaster planning to national security to housing standards.

At the Interior Department, decisions about Pacific island territories threatened by rising seas are in the hands of an assistant secretary who has criticized "climate alarmists" for "once again predicting the end of the world as we know it." Agriculture Secretary Sonny Perdue's top advisers include a former talk radio host who has dismissed much climate research as "junk science." Trump's nominee to head research and technology at the Department of Transportation claimed three years ago that global warming had "stopped" — a position at sharp odds with the findings of federal agencies like NASA.

Trump has chosen at least 20 like-minded people to serve as agency leaders and advisers, according to a POLITICO review of his appointees' past statements on climate science. And they are already having an impact in abandoning former President Barack Obama's attempt to help unite the world against the threat of rising sea levels, worsening storms and spreading droughts.

[Sneak preview for Pro subscribers: Trump's climate science doubters]

Most famously, the president and his team have scrubbed mentions of climate change from government websites, kicked scientists off advisory boards, repudiated the Obama administration's greenhouse gas regulations and made the U.S. the only nation on Earth to reject the 2015 Paris agreement on global warming.

More quietly, Trump's White House excluded rising temperatures from the list of threats in its December national security strategy, contradicting the approach of both the Obama and George W. Bush administrations. Last year, just before Hurricane Harvey drowned Houston, the White House rescinded requirements that projects built with federal dollars take into account the way warming temperatures might intensify extreme weather.

People worried about the consequences of climate change say a government that denies the problem is courting danger.

"The analogy could be if somebody's got a heart problem or high cholesterol, you take medicine that helps manage that so you can avoid a heart attack," said Ana Unruh Cohen, the government affairs director at the Natural Resources Defense Council. "Trump taking that away, saying, 'Forget it, I don't believe I have high cholesterol,' is setting up the country for a heart attack."

Aparna Mathur, a resident scholar in economic policy at the conservative American Enterprise Institute, found the trend worrying as well.

Many administration officials "don't seem to believe climate change is real, or if they believe climate change is real, there's this sort of attitude that there's not much to do about it or it's not caused by human actions," said Mathur, whose AEI colleagues also include people who question the extent of man-made climate change. As a result, she said, the U.S. is falling behind countries that are taking action on the problem.

The doubts are coming from both prominent and little-known Trump appointees, in ways both obscure and subtle.

Some have expressed doubt that the Earth is warming at all, speculated that the trend might be good for humans, or said it's just impossible to know how much of a role humans and their pollution are playing. All these statements fly in the face of findings by the government's own research agencies and the vast majority of climate scientists.

"There are scientists that think lots of different things about climate change," then-Rep. Mike Pompeo (R-Kan.), now Trump's CIA director, said on C-SPAN in 2013. "There's some who think we're warming, there's some who think we're cooling, there's some who think that the last 16 years have shown a pretty stable climate environment." Pompeo dodged the issue in his confirmation hearing last year, saying he would "prefer today not to get into the details of the climate debate and science."

When he was running for president, HUD Secretary Ben Carson scoffed at the idea that strong evidence for human-caused climate change even exists. "I know there are a lot of people who say 'overwhelming science,' but then when you ask them to show the overwhelming science they never can show it," he told the San Francisco Chronicle in 2015.

Few have been as publicly outspoken on the issue as Trump, who more than once has dismissed human-caused climate change as a "hoax" and claimed in January that polar ice isn't melting.

The White House sought to strike a somewhat more moderate tone in a statement to POLITICO on Monday, which said that "the climate has changed and is always changing. The Administration supports rigorous scientific analysis and debate." The statement from principal deputy press secretary Raj Shah added that "the development of modern and efficient infrastructure ... will reduce emissions and enable us to address future risks, including climate related risks."

Some of the administration's climate skeptics have already come and gone.

Former HHS Secretary Tom Price, who had criticized the "allegedly 'settled science' of global warming" as a member of Congress, resigned in September amid criticism of his expensive travels on government and private planes. Kathleen Hartnett White, Trump's pick to head the White House Council on Environmental Quality, withdrew her nomination earlier this year after she stirred criticism with a long list of controversial statements , including calling the human role in climate change "very uncertain."

Another unsuccessful nominee, former talk radio host and political science professor Sam Clovis, had to pull out of the running to be USDA's chief scientist after critics noted that he has no science credentials — but he remains a top adviser to Perdue. Clovis dismissed much climate research as "junk science" in a 2014 interview, adding that "a lot of this global warming ... is really about income redistribution from rich nations that are industrialized to nations that are not."

Brent Fewell, a conservative environmental lawyer who was an EPA water official under Bush, suggested that some of these officials may privately acknowledge that man-made climate change is real. But he added: "A lot

of people on the political right are uninformed about the issue. For whatever reason, it's a lot easier to simply agree with the prominent voices in the political party."

The upshot is the same, however: a 180-degree reversal from Obama's efforts to make the U.S. a leader in addressing the causes and consequences of a warming planet.

The EPA is leading the charge by withdrawing or weakening a host of climate regulations, including a 2015 rule that would have sped the electric power industry's shift away from coal-fired energy. Trump has also approved tariffs for solar panel imports, which will make it harder for green energy to compete with fossil fuels. Agencies have sought to cancel rules meant to limit the oil and gas industry's methane pollution — another major greenhouse gas source — and are reconsidering tougher standards for vehicles, too.

The Energy Department has proposed regulatory changes to prop up coal plants that can't compete in the market, while the White House is seeking buyers for U.S. coal and gas exports.

When Trump's critics seek to challenge these actions in court, the government's defense will be run by the Justice Department — an agency whose leader, Attorney General Jeff Sessions, said during a 2015 Senate hearing that carbon dioxide is "really not a pollutant."

"It's a plant food, and it doesn't harm anybody except that it might include temperature increases," Sessions said.

Some agencies are still continuing to study climate change and factor their findings into their policy decisions. But even there, career staffers may not talk about their work as openly as they once did, and the agencies seldom showcase it the way they did during the Obama years.

Much of the alarm among Trump's critics focuses on EPA, which has replaced dozens of scientists on its key advisory boards with industry or state representatives, and has found other ways to keep researchers from contradicting the administration's message. Last fall, the agency canceled an appearance by three EPA scientists scheduled to speak about climate change at a Narragansett Bay conference . Both EPA and the Energy Department have given extra scrutiny to grant proposals with the words "climate change," and in the case of EPA, it has put a political appointee in charge of signing off on them, The Washington Post has reported.

All this is in line with the public statements of EPA Administrator Scott Pruitt, who has suggested that global warming might be a good thing and has spoken about holding a public debate on whether climate change is real.

"Right out of the gate ... the administration took any and all mention of climate change off of the White House website," said Jacob Carter, a research scientist who has been tracking the administration's treatment of science for the Union of Concerned Scientists. "It seems like the administration is really trying to undo a lot of the scientific process as a whole and get experts out of the way."

The Environmental Data and Governance Initiative, which has studied the purging and rewording of climate-related documents on government websites, reported at the end of 2017 that it had found a "significant loss of public access to information about climate change."

The State Department's website took down links related to the Paris climate agreement, EPA removed a student's guide to climate change, and the Energy Department got rid of the words "clean energy" on a page with information for investors and businesses looking for projects with national laboratories.

The Interior Department's Bureau of Land Management, which oversees energy development on federal land, cut text about the effects of climate change. Some of the resources are still technically available in archives or in new locations, but they are harder to find because the government sites don't directly link to them, the Environmental Data and Governance Initiative says.

"It's not alarming the public because it's very hard to see each incremental thing," said Andrew Bergman, a co-author of the report.

Some Trump appointees have downplayed the idea that agency leaders' personal views about climate change are critical to making policy, suggesting they can still respond to global warming's effects without addressing why it's happening.

"We continue to take seriously climate change — not the cause of it, but the things that we observe," Tom Bossert, the president's homeland security adviser, told reporters after last year's spree of catastrophic hurricanes that ravaged Houston, Puerto Rico and the Virgin Islands.

Sarah Hunt, who works in energy policy at the conservative American Legislative Exchange Council, said that "policymaker views on climate science needn't have any bearing on their support for conservative clean energy policies that spur the innovation we need to reduce emissions and promote environmental stewardship while we grow our economy."

But Trump's actions have reflected his views on the science. For example, one of his early executive orders in March 2017 eliminated a number of ways agencies had been required to consider climate change, including in environmental reviews for infrastructure projects.

Because so many of his appointees have questioned the conclusions of climate scientists, they are jettisoning climate change from routine processes. Those include EPA's refusal to consider the global monetary benefits of curbing rising temperatures when it rolled back Obama-era rules for the power sector.

Still, some agencies have continued to issue major reports that warn that climate change is a real and growing problem — even as the president's staffers push the message that the science is uncertain.

In November, the government's 13-agency National Climate Assessment concluded that humans have pushed global temperatures to their highest level in modern times. In January, NASA published data showing that last year was the second-warmest on record, and noted that temperature rises are "driven largely by increased carbon dioxide and other human-made emissions into the atmosphere."

Trump's nominee to run the space agency, Rep. Jim Bridenstine (R-Okla.), criticized "climate change alarmists" on the House floor in 2013 and claimed that "global temperatures stopped rising 10 years ago." (In fact, they haven't.) At his confirmation hearing last year, he acknowledged that humans are a cause of climate change but wouldn't call them the main cause.

"That is a question that I do not have an answer to," he said.

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House panel green-lights Commerce-Justice-Science bill Back

By Hugh T. Ferguson and Sarah Ferris | 05/17/2018 04:19 PM EDT

The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill, marking its fifth completed bill of the spending cycle. The vote was 32-19, along party lines.

In a rare bipartisan moment in the five-hour markup, lawmakers agreed to add a provision to uphold sanctions against the Chinese phone-maker ZTE, just days after President Trump declared he is seeking to lessen the penalties.

Another bipartisan addition would protect medical marijuana in states where it's already legal — language that was skipped over in last year's markup but adopted this year with barely an objection.

The fiscal 2019 measure would provide $62.5 billion for the wide-ranging Commerce-Justice-Science bill, which funds federal law enforcement, NASA and the National Science Foundation, a $2.9 billion bump above current levels.

The bill would fund the Department of Justice at $30.7 billion, an increase of $793 million from fiscal 2018. Within that, the FBI's budget would dip slightly, although it is still $400 million more than the White House request.

The budget for the U.S. Census would swell to $4.8 billion, nearly double the current levels, as officials ramp up for the 2020 survey.

NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request.

Another $447 million would go toward the national fight against opioid addiction, the same amount in this year's omnibus, H.R. 1625 (115).

House Democrats, along with a pair of Republicans, offered 18 amendments. Many were targeting specific riders that they viewed as partisan threats to the measure's passage.

The panel also unanimously backed a manager's amendment from subcommittee Chairman John Culberson (R-Texas). The amendment contained a number of provisions that each side had agreed upon, according to Culberson and Rep. José Serrano (D-N.Y.) ranking member of the subcommittee.

Amendments included:

— Barbara Lee (D-Calif.) amendment that would strip the measure of three firearm related provisions with the intent to reduce gun violence, rejected 20-31.

— Matt Cartwright (D-Pa.) amendment that would increase funding for the NOAA climate research program, withdrawn.

— Nita Lowey (D-N.Y.) amendment that would prevent individuals from purchasing a firearm by giving the attorney general the authority to deny the sale of a firearm to an individual buyer believed to be aiding in acts of terrorism, rejected 20-31.

— Lucille Roybal-Allard (D-Calif.) amendment that would prohibit the use of funds to prosecute immigrants who have illegally entered the U.S. seeking asylum unless they have committed serious criminal acts or present a danger to the U.S., rejected.

— David Price (D-N.C.) amendment related to eviction proceedings with competitive grant funding for legal services in high eviction areas, rejected 22-28.

— Dave Joyce (R-Ohio) amendment related to protections for state medical marijuana laws, adopted on voice vote.

— Dutch Ruppersberger (D-Md.) amendment related to moving the FBI into a new headquarters, withdrawn.

— Betty McCollum (D-Minn.) and Tom Cole (R-Okla.) amendment related to funding increase for tribal nations under the Crime Victims Fund, adopted on voice vote.

— Derek Kilmer (D-Wash.) amendment related to increasing funding for coastal resilience programs at NOAA, withdrawn.

— Debbie Wasserman Schultz (D-Fla.) amendment related to restoring stricter reporting rules for certain semi-automatic guns, rejected by voice vote.

— Henry Cuellar (D-Texas) amendment related to protecting land by limiting the government's eminent domain powers when it comes to building a border wall, rejected by voice vote.

— Ruppersberger amendment related to enforcing sanctions against ZTE, adopted by voice vote.

— Lowey amendment protecting the special counsel at the Department of Justice, rejected 23 to 27.

— Grace Meng (D-N.Y.) amendment related to increasing funding for juvenile delinquency prevention programs, withdrawn.

— Serrano amendment related to the new citizenship question on the 2020 U.S. Census, rejected by voice vote.

— Ruppersberger amendment related to federal grants tackling contraband cellphone use in prisons.

— Andy Harris (R-Md.) amendment related to DEA research on medical risks and benefits of marijuana, withdrawn.

— Ruppersberger amendment related to NASA satellite program, withdrawn.

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NATO chief thanks Trump for leadership on military spending Back

By Eli Okun | 05/17/2018 03:26 PM EDT

NATO Secretary-General Jens Stoltenberg praised President Donald Trump on Thursday for pushing countries in the alliance to boost their defense spending, an issue that has driven a wedge between Trump and Europe before.

"Let me thank you for the leadership you show on the issue of defense spending because it is very important that we all contribute more to our shared security, and it is really having an impact because, as you said, allies are now spending more on defense," Stoltenberg said while taking reporters' questions after the leaders met at the White House. "All allies are increasing their defense budgets."

"Do you give me credit for that?" Trump pressed.

"You have helped to do that," Stoltenberg said.

It was a notable moment for a U.S.-NATO relationship that has sometimes seemed on shaky ground during the Trump administration.

A minority of NATO's members — including the U.S. — meet the alliance's nonbinding guideline for each country to spend at least 2 percent of its GDP on defense.

Other American presidents have pressed their NATO allies to increase military budgets. But the issue has become a particular flashpoint for Trump, who is often skeptical of international alliances or deals that he deems unfair to the U.S.

"Together we've increased and really raised a lot of money from countries that weren't paying, or weren't paying a fair share," Trump said on Thursday. "We have a little ways to go, but many billions of dollars of additional money has been raised."

Stoltenberg later told the president: "Your leadership on defense spending has really helped to make a difference."

Trump noted that he thought the alliance should increase the standard to 4 percent.

Last year, Trump reversed his previous dismissals of the alliance and said he no longer considered NATO "obsolete." But he's continued to raise concerns about spending — including to Chancellor Angela Merkel of Germany last month.

Trump again singled out Germany on Thursday, calling it "a very big beneficiary" that "must demonstrate leadership."

And though Trump said the alliance needed to improve its counterterrorism capabilities, he repeated that the U.S. was committed to NATO's Article 5.

Early in his administration, Trump scared European allies by deciding on the fly to scrap a public affirmation of Article 5, the longstanding lynchpin of the alliance that guarantees the countries' commitment to mutual defense. But by June 2017, he committed to the article.

Though the president's decision last week to abandon the Iran nuclear deal angered European allies, Secretary of State Mike Pompeo, who took office last month, has made a more positive impression on NATO so far.

The leaders' meeting came ahead of a NATO summit in July.

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EPA watchdog: Investigator says he did not socialize with Pruitt security chief Back

By Alex Guillén | 04/13/2018 05:46 PM EDT

A top investigator at EPA's Office of Inspector General is disputing a report that he is friends with the head of Administrator Scott Pruitt's protective detail, according to a spokeswoman for the internal watchdog.

The New York Times reported Thursday that Patrick Sullivan, the assistant IG in charge of investigations, has been seen drinking beers at a bar across the street from EPA's headquarters with Pasquale "Nino" Perrotta, who last year became the head of Pruitt's security detail after his predecessor was removed.

Citing that report, a left-leaning nonprofit group on Friday requested an investigation from a council of federal inspectors general. But Sullivan says the Times got it wrong.

Sullivan "confirmed that he has never had drinks with Mr. Perrotta anywhere or at any time. He has never been to the Elephant and Castle with Mr. Perrotta," IG spokeswoman Tia Elbaum said in an email Friday.

While they had both previously worked for the Secret Service, Sullivan and Perrotta did not know one another until Sullivan began working for the EPA IG in 2011, according to Elbaum. "They are professional colleagues and friendly, but do not socialize outside of work," she said. (Perrotta, who has become a key figure in some of the controversies surrounding Pruitt, arrived at EPA in 2004, and initially worked at the OIG but moved to the security detail before Sullivan was hired.)

Another spokesman for the OIG said they have not yet asked for a retraction but may do so in the future.

A spokesperson for the Times said the paper stands by its story.

The watchdog group Citizens for Responsibility and Ethics in Washington on Friday asked for an investigation into their relationship.

The alleged socialization is "conduct that may undermine the independence or integrity reasonably expected of Mr. Sullivan," wrote CREW in a letter to officials at the independent Council of the Inspectors General on Integrity and Efficiency.

The Times did not specify the source or sources who claimed to have spotted Sullivan and Perrotta having drinks, but its original report said a spokesman for EPA's inspector general had disputed that the two men socialized outside of work. The story does not appear to have been updated since it was first published.

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Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 5/18/2018 9:49:28 AM
To: Dravis, Samantha [dravis.samantha@epa.gov]
Subject: Morning Energy, presented by Chevron: Another House WOTUS vote ... maybe — Trump signs efficiency EO — More calls for release of chemical safety study

By Kelsey Tamborrino | 05/18/2018 05:43 AM EDT

With help from Anthony Adragna and Annie Snider

ANOTHER HOUSE WOTUS VOTE ... MAYBE: The House is scheduled to vote today on an amendment to the farm bill, H.R. 2 (115), from Indiana Republican Rep. Jim Banks that would repeal the Obama administration's Waters of the U.S. rule. Provisions targeting the rule, which is deeply reviled in farm country, have been approved repeatedly, including when attached to appropriations measures, only to be stripped in the end. But WOTUS opponents keep hoping that the stars will align for them on a must-pass bill.

Banks touted the amendment on a local radio show Thursday. "With the farm bill on the floor, I thought, 'Well, this is a natural place to fully and permanently repeal WOTUS once and for all," he said, adding that groups like Heritage Action, the U.S. Chamber of Commerce and Club for Growth, have backed his amendment. "This is a rule that scares not just farmers, but a lot of property owners and developers and people who understand that this is federal government going way too far," he added.

The farm bill may not be that measure, though — at least not right now. As Helena Bottemiller Evich, Liz Crampton and Rachael Bade report, the House Freedom Caucus is threatening to scuttle the bill unless a vote on conservative immigration legislation is held first. House GOP leaders maintain lawmakers will still vote on the legislation today, despite the threat.

Separately, 40 environmental groups — including the League of Conservation Voters, Earthjustice and the Sierra Club — signed onto a letter urging House lawmakers to reject the amendment. "It's really this simple: a vote for this rider is a vote against clean water, a vote to expose even more communities to unsafe drinking water, a vote to limit the scope of the Clean Water Act, and a vote to allow polluters to destroy our precious waterways," they write.

The House is scheduled to meet at 9 a.m. for legislative business, with first and last votes expected between 10:30 a.m. and 11:30 a.m. See the full list of amendments here.

GET A WRDA IN EDGEWISE: Meanwhile, the House Transportation Committee will release its own Water Resources Development Act today, the committee's chairman said. The bill is expected to differ significantly from the Senate's version that will be marked up Tuesday, Pro's Annie Snider and Anthony Adragna report, but it does have the support of the committee's ranking member Peter DeFazio and the top Democrat and Republican on the Water Resources and Environment Subcommittee. GOP Rep. Garret Graves, the subcommittee chairman, said the House measure will include language relating to one of his top priorities: moving the Army Corps of Engineers out of the Defense Department. On the Senate side, both Democrats and Republicans have been wary of that idea. However, Graves indicated the House bill will not make that move immediate.

WE MADE IT TO FRIDAY! I'm your host Kelsey Tamborrino. Turns out there are a few different ways to answer yesterday's trivia question. But I'm giving the win to LCV's Gene Karpinski, who was the first to identify Rock Creek Park, authorized in 1890, as what the National Park Service calls the third national park to

be designated by the federal government. For today, a related question: William Henry Jackson was the first person to photograph Yellowstone. What monument is home to the largest single holding of his paintings? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy, and @POLITICOPro.

TRUMP SIGNS EFFICIENCY EO : President Donald Trump signed an executive order late Thursday to prioritize efficiency in the government. The order calls on agencies to "prioritize actions that reduce waste, cut costs, enhance the resilience of Federal infrastructure and operations, and enable more effective accomplishment of its mission." It focuses on increasing efficiency of federal buildings and vehicles in a cost-effective manner. The president also directed the Council on Environmental Quality and the Office of Management and Budget to streamline energy and environmental requirements, in a simplified and accountable manner. Last year, the White House said, agencies spent more than $6 billion on energy for buildings and $635 million on water. Within 90 days, the Agriculture and Energy secretaries and the administrators of EPA and General Services, are tasked with reviewing relevant established government-wide guidance and in conjunction with CEQ, must "develop a plan and proposed timeline to modify, replace, or rescind such guidance, as necessary."

But the order also notably rescinds an Obama-era order from March 2015 that focused on sustainability, requiring agencies to slash its greenhouse gas emissions and address climate change. That EO set a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years. Trump's order makes no mention of climate change or emissions reductions. Instead it calls on agencies to track and report greenhouse gas emissions. Read the order here.

SENATE'S 'BIG FOUR' ON NUCLEAR WASTE PLAN MEETING: A bipartisan group of four senior senators are planning to get together in hopes of launching a new push on nuclear waste legislation, according to Sens. Lisa Murkowski and Lamar Alexander. "Our staffs have been working, but I don't know if a date has been set," Murkowski, chairman of the Energy Committee, told ME. Their Democratic counterparts at the meeting would be Sens. Dianne Feinstein and Maria Cantwell. The planned meeting comes after the House passed its own broad nuclear waste overhaul that would move the Yucca Mountain repository forward.

SIMPSON STILL 'LEANING NO' ON RESCISSIONS: Rep. Mike Simpson, who chairs an Appropriations panel responsible for DOE funding, says he's "leaning no" on a proposed list of $15.4 billion in cutbacks from the administration but plans to continue his review of it. "I want to look at the loan guarantees," he told reporters. "Most of them are probably going to be OK. There some that might not be." Remember Simpson's one of several senior Appropriators who've expressed reservations about the package.

BARRASSO STILL CONCERNED ABOUT PRUITT: Senate EPW Chairman John Barrasso says he isn't giving EPA Administrator Scott Pruitt a free pass even as he remains non-committal about when he'll haul the embattled EPA chief before his committee. "I still have lots of concerns with regards to spending issues," he told reporters. "I continue to send and ask questions."

ALL IN THE TIMING: Depending on when Pruitt created his legal defense fund, onlookers may have to wait another year to see who donated. As E&E News reports, the embattled EPA chief is required to report gifts received on his public financial disclosure report, which would include contributions to the legal defense fund established for his benefit, according to guidance on the Office of Government Ethics' website. But those reports are only filed once a year, meaning if Pruitt's defense fund was created this year, he'd report it for the 2018 calendar year, which isn't required to be filed until May 2019 at the earliest. Of course, that means if Pruitt created the fund in the 2017 calendar year, it would be in the financial disclosure report that Pruitt recently got an extension to file. Read more.

BRIDENSTINE: 'GREENHOUSE GAS IS WARMING THE PLANET': NASA's Jim Bridenstine held his first town hall as administrator Thursday, where he clarified his stance on climate change. He said his position

on the issue has "evolved," and he described the impact of tornadoes in his home state. "I don't deny the consensus that the climate is changing, in fact I fully believe and know that the climate is changing," Bridenstine said. "I also know that we human beings are contributing to it in a major way." The former Oklahoma lawmaker, who was recently confirmed to the agency, faced previous criticism from Democrats over his denial that climate change is caused by humans. During Thursday's address, Bridenstine instead praised the work of NASA and defined carbon dioxide as a greenhouse gas. "We're putting it to the atmosphere in volumes that we haven't seen and that greenhouse gas is warming the planet," he said. "That is absolutely happening and we are responsible for it." Watch his remarks here.

MORE CALLS FOR RELEASE OF CHEMICAL SAFETY STUDY: Calls continue to mount for the Trump administration to release a hot-button assessment of the chemicals PFOA and PFOS that POLITICO reported Monday was described as a "public relations nightmare" by a White House official. New York Democratic Rep. Sean Patrick Maloney will add his voice to the chorus with a letter to Pruitt today. Maloney's Hudson River Valley district includes Newburgh, N.Y., where the chemicals have leached from the nearby Stewart Air National Guard Base. State-funded blood tests have found that residents there have more than three times the amount of PFOS in their blood than the average American.

HOUSE APPROPRIATIONS SCIENCE BILL ADVANCES: The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill Thursday on a party-line vote of 32-19. The fiscal 2019 measure would increase spending for federal law enforcement, NASA and the National Science Foundation by $2.9 billion to a total of $62.5 billion, Pro's Hugh Ferguson and Sarah Ferris report. NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request. Among the 18 amendments offered, two Democrat-offered NOAA-related ones were withdrawn. One was related to increasing funding for coastal resilience programs at NOAA, and another would increase funding for the NOAA climate research program.

Speaking of NOAA: The agency found April 2018 marked the 400th consecutive month with temperatures above average. Additionally, NOAA said the average global temperature for April was 1.49 degrees F above the 20th-century average of 56.7 degrees — the third highest for April in the 139-year record, with 9 out of the 10 warmest Aprils occurring since 2005.

CLIMATE CAUCUS WELCOMES FIVE MEMBERS: The Climate Solutions Caucus welcomed five new members to its ranks on Thursday: Reps. Erik Philip Paulsen, Tom MacArthur, Eliot Engel, Peter Roskam and Ron Kind. The additions bring the bipartisan caucus' total to 78 members.

CORPS GRID RESTORATION ENDS TODAY: At the direction of the CEO of the Puerto Rican power company PREPA and the Energy Unified Command Group, FEMA said that as of today the Army Corps of Engineers will no longer provide line restoration work for the power authority. Instead, PREPA will oversee its contractors and the remaining work in grid restoration. PREPA reports 98.86 percent of pre-storm customers have had their power restored, with 16,723 remaining without power, as of Wednesday.

But FEMA said Thursday it had approved the extension of an Army Corps mission assignment that allows for the lease, generation and maintenance of three "mega generators" until PREPA completes its purchase of the generators.

NATURAL GAS AND NATO: Although it was not immediately clear how, Trump said Thursday gas would play a role in upcoming NATO talks. The president remarked on Germany's relationship with Russia during his meeting with Secretary-General Jens Stoltenberg, who praised Trump for pushing countries in the alliance to boost their defense spending. In his remarks, Trump specifically called out Germany for its "longstanding shortfall in defense contributions." Trump called the member nation "a very big beneficiary" that "must demonstrate leadership." He added, "they're buying massive amounts of gas from Russia and paying billions

and billions of dollars. So I think that's something we'll be discussing later and we'll be discussing that at our meeting, and probably long before the meeting." The leaders' meeting came ahead of a NATO summit in July.

Meanwhile, The Wall Street Journal reported on Thursday that U.S. and European officials said Trump told German Chancellor Angela Merkel in April that Germany should drop support for Nord Stream 2, an offshore pipeline that would bring gas directly from Russia via the Baltic Sea. This would be in exchange for the U.S. starting talks with the European Union on a new trade deal.

DEPARTMENT OF CORRECTIONS: The New York Times set the record straight last night, issuing a correction to its story from April 13 that said the former head of Pruitt's security detail, Pasquale "Nino" Perrotta, had met for drinks with an an official from the EPA inspector general's office. That report had raised concerns in some quarters about the independence of the IG investigator.

The story, the paper said, "erroneously included Mr. Perrotta among those who gathered for beers at an event at the Elephant and Castle in Washington that was attended by Patrick Sullivan, the assistant inspector general who oversees investigations at the E.P.A. Mr. Sullivan said that Mr. Perrotta had been invited but did not attend that gathering and that he has never met for drinks with Mr. Perrotta, though he acknowledged that the two men met for lunch several months later at another restaurant near the E.P.A. headquarters."

MAIL CALL! Democratic Sens. Ed Markey, Sheldon Whitehouse and Tom Carper , members of the EPW Committee, called on EPA to publicly release a health assessment on the effects of formaldehyde exposure. They cite an exchange between Markey and Pruitt during his January appearance before the committee where Pruitt said he'd get back to the senator on the progress of the report. "Unfortunately, it appears that the agency may be succumbing to pressure from industry in its attempt to delay or block the publication of the formaldehyde health assessment," they write. Read it here.

CONGRATS ARE IN ORDER: Barrasso congratulated Wyoming Gov. Matt Mead in a letter this week on the dedication of the state's Integrated Test Center near Gillette. The carbon capture research facility, dedicated Wednesday, is a testing space off the back of the operating coal power plant. Five Carbon XPrize finalists — U.S., Canada, India, China and Scotland — will head to the site to put their concepts to capture CO2 from the power plant and convert it to a marketable product to the test. In his letter, Barrasso called the ITC "an important resource for Wyoming's economy." Read it here.

ROCKET TO THE SUN: House Science Chairman Lamar Smith said Thursday he submitted the names of committee members and staff to be placed aboard the Parker Solar Probe on its "mission to touch the Sun." NASA opened up the opportunity to the public to submit names to be stored on a memory card and installed on the probe before it launches this summer. "When I came across NASA's unique offer, I thought this would be a perfect and light-hearted opportunity to carve the names of the members and staff in history," Smith said in a statement.

SEE IT: Electricity generation will vary widely over the coming decades, according to U.S. Energy Information Administration's projections. Pro's DataPoint team breaks down the numbers in a graphic here. Want to add DataPoint to your Pro account? Learn more.

QUICK HITS

— Florida congressional delegation gives thumbs-down to offshore drilling, McClatchy.

— Republican lawmaker: Rocks tumbling into ocean causing sea level rise, E&E News.

— Emails show Interior expected to learn nothing from public input on Bears Ears review, Huffington Post.

— Zinke moves to protect critical minerals from foreign threats, Washington Examiner.

— Zinke tells greens he'll make 'grand pivot' to conservation, E&E News.

— Will Trump's pick to run EPA in California show up for work? Los Angeles Times.

HAPPENING TODAY

9:00 a.m. — House Energy and Commerce Environment Subcommittee hearing on various bills, 2123 Rayburn

9:30 a.m. — House Judiciary Regulatory Reform, Commercial and Antitrust Law Subcommittee hearing on "No Oil Producing and Exporting Cartels Act," 2141 Rayburn

12:00 p.m. — The National Capital Area Chapter of the United States Association for Energy Economics presentation on "How less-than-efficient humans interact with energy markets," 618 H St NW

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https://subscriber.politicopro.com/newsletters/morning-energy/2018/05/another-house-wotus-vote-maybe-222339

Stories from POLITICO Pro

GOP leaders, Freedom Caucus face off on farm bill, immigration Back

By Liz Crampton, Helena Bottemiller Evich and Rachael Bade | 05/17/2018 04:34 PM EDT

House GOP leaders are daring the Freedom Caucus to sink their prized partisan farm bill, pushing ahead with a Friday morning vote despite conservative threats to tank it.

Speaker Paul Ryan's team haggled late into the night Thursday with Freedom Caucus leaders. To win the far-right, leaders gave the group what it originally asked for: the promise of a vote on a conservative immigration bill — albeit not until June.

But the Freedom Caucus retorted that they want the immigration roll call now before the farm bill gets a vote. Some fear leadership will renege on that vow, as they have on the issue in the past.

After Ryan's team explained to the group late Thursday that they could not do immigration before the farm bill, the group of conservatives held a conference call to discuss what to do.

With the vote still scheduled for Friday morning, it is unclear where things stand. GOP leaders are waiting for word on whether the Freedom Caucus will deliver the final votes needed to push the bill over the finish line. President Donald Trump, meanwhile, tweeted about the matter, asserting pressure on the right to get in line.

"Tomorrow, the House will vote on a strong Farm Bill, which includes work requirements," Trump wrote, referring to a new mandate in the bill requiring those receiving food stamps to find employment. "We must support our Nation's great farmers!"

Tensions over the farm bill escalated Thursday afternoon when Freedom Caucus Chairman Mark Meadows announced that his three-dozen members would not support the measure. In return for their vote, the North Carolinian said they'd need a vote on a bill crafted by Judiciary Chairman Bob Goodlatte that extends Dreamers' legal status for a host of conservative immigration policies.

"At this point there is no deal to be made," Meadows said exiting an hour-long Freedom Caucus powwow. "The vast majority of our members believe we should have a vote on immigration before the farm bill."

He added: "At this point there's not enough votes to pass the farm bill."

Even after the group rejected that offer, House Majority Leader Kevin McCarthy maintained that he was not pulling the bill from the floor. Senior Republicans are holding out hope that they could reach some sort of accord by Friday.

The scheme by conservatives could throw at least a temporary wrench in Ryan's welfare overhaul push. The farm bill, which covers agriculture subsidies, conservation, rural development and nutrition, would impose stricter work requirements on between 5 million and 7 million food-stamp recipients. The current farm bill expires Sept. 30.

With Democrats planning to vote against the farm bill because of the new work requirements, Republicans need the votes of the Freedom Caucus for the measure to pass.

The scramble to try to bring the bill to a vote this week highlights the deep divisions within the Republican Conference. On the right, conservatives have been lukewarm at best on the sweeping bill, arguing it both doesn't go far enough on work requirements for able-bodied adults receiving food stamps, and does nothing to rein in farm subsidies. Several Republican moderates, meanwhile, have quietly raised concerns about the work requirements.

Ryan has long been eyeing the bill as a rare chance to enact a piece of a welfare overhaul, a key priority for the outgoing speaker. It's the first farm bill cycle in decades where Republicans control both chambers of Congress and the White House.

Even if the leaders strike a deal with conservatives, the version of the bill is considered a nonstarter in the Senate. Senate Agriculture Chairman Pat Roberts (R-Kan.) and ranking member Debbie Stabenow (D-Mich.) are drafting a bipartisan bill. Roberts has said the Senate will not include work requirements, citing his need to get 60 votes.

The food stamp program, now formally known as the Supplemental Nutrition Assistance Program, helps more than 40 million low-income Americans buy groceries each month.

The program has long had bipartisan support as well as backing from large food companies and retailers, who now see SNAP as big business. But SNAP's rolls expanded greatly in the wake of the Great Recession, and while the numbers have come down somewhat, they have not returned to pre-recession levels.

While the farm bill has historically been passed by a coalition of urban and rural lawmakers from both sides of the aisle, talks between Republicans and Democrats broke down earlier this year in the House Agriculture Committee over the work requirements, making the process unusually bitter and partisan.

"The farm bill also keeps faith with these families by not only maintaining SNAP benefits but by offering SNAP beneficiaries a springboard out of poverty to a good paying job, and opportunity for a better way of life for themselves and their families," House Agriculture Chairman Mike Conaway (R-Texas) said when he unveiled the bill last month.

The bill would require adult SNAP recipients between the ages of 18 and 59 to work or be enrolled in a training program at least 20 hours per week. People who are disabled, pregnant or caring for a child under the age of 6 would be exempt. The plan would also expand the pool of money for state-run work training programs tenfold, from $90 million per year to $1 billion.

The plan to go along with a GOP-only farm bill was originally Ryan's, according to senior Republican sources. The bill is seen as a personal priority for the speaker, who will retire at the end of the year and has long eyed enacting comprehensive welfare reform.

With leadership relying only on Republican votes for the bill, the House Freedom Caucus saw their opportunity for leverage.

Meadows acknowledged that the farm bill is the last must-pass legislation before the federal government spending bill must be approved in October. "Obviously when you look at that it's a leverage point," he said.

Catherine Boudreau contributed to this report.

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Shuster: House WRDA bill coming Friday Back

By Annie Snider and Anthony Adragna | 05/17/2018 03:14 PM EDT

The House Transportation and Infrastructure Committee will release its Water Resources Development Act Friday, Committee Chairman Bill Shuster said.

The measure has the support of the committee's ranking member, Rep. Peter DeFazio (D-Oreg.), as well as the top Democrat and Republican on the Water Resources and Environment Subcommittee, according to Rep. Garret Graves (R-La.), chairman of that subcommittee.

The House bill is expected to differ significantly from the upper chamber's measure. Graves said it will include language relating to one of his top priorities, moving the Army Corps of Engineers out of the Defense Department. Both Democrats and Republicans on the Senate Environment and Public Works Committee have been wary of that idea. However, Graves indicated the House bill will not call for an immediate move.

"There's a number of steps to the process in terms of how I think this will ultimately be done," Graves told POLITICO. "We do need to take a careful, constructive path forward because you don't want to come in and do something that's actually going to make it worse."

The Senate EPW Committee plans to mark up its bill next Tuesday, Committee Chairman John Barrasso (R-Wyo.) said today. He said he has not spoken with his House counterparts about their bill in the last couple of days and said the chambers are not coordinating their efforts.

WHAT'S NEXT: The House Transportation and Infrastructure Committee is expected to unveil its WRDA bill Friday. A markup could come as soon as next week.

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Obama touts climate executive order: Back

By Andrew Restuccia | 03/19/2015 12:02 PM EDT

President Barack Obama said this morning that his administration is "leading by example" by requiring the government to slash its greenhouse gas emissions.

"This has been a team effort to make sure that we're doing everything we can to boost the energy efficiency of the federal government," Obama said during brief remarks at the Energy Department.

And he made the case that policymakers can deal with climate change, while also protecting the economy.

"We're proving that it's possible to grow our economy robustly, while at the same time doing the right thing for our environment and tackling climate change in a serious way," he said.

Obama signed an executive order this morning that sets a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years.

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House clears nuclear waste bill that would move Yucca forward Back

By Anthony Adragna | 05/10/2018 11:27 AM EDT

The House today cleared nuclear waste legislation, H.R. 3053 (115), that would kick-start the stalled Yucca Mountain repository while also establishing an interim storage facility for spent nuclear waste.

Overcoming the strong objections of Nevada lawmakers, the bill passed 340-72, with bipartisan support. It would offer incentives to the state for allowing Yucca to advance, include federal land transfers associated with the site and change how user fees are collected to help build the repository, among other provisions.

"I think people are ready to do something rather than nothing," Rep. John Shimkus (R-Ill.), the bill's sponsor, told reporters earlier this week.

Key to getting the bill to the floor was breaking a monthslong "impasse" with House Appropriators on how to spend revenues collected through the Nuclear Waste Fund, an account containing tens of billions built on fees on nuclear-generated electricity. Shimkus said his compromise will allow lawmakers "be more honest brokers" going forward by walling off future collected fees from being spent on other programs.

Lawmakers rejected an amendment from long-time Yucca opponent Rep. Dina Titus (D-Nev.) concerning consent-based siting, while adopting other amendments requiring clearer annual reports on the Nuclear Waste Fund balance and a report on resources for communities dealing with nuclear waste issues.

WHAT'S NEXT: Shimkus said he doesn't expect to see the bill taken up in the Senate, where Yucca opponent Sen. Dean Heller (R-Nev.) faces a competitive reelection.

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Some GOP appropriators resist Trump cutbacks Back

By Sarah Ferris and Kaitlyn Burton | 05/11/2018 05:03 AM EDT

Several GOP spending chiefs have cast doubt on President Donald Trump's proposed list of $15.4 billion in cutbacks, saying they're not yet ready to bury some of the targeted programs.

White House officials have pitched their rescissions package, H.R. 3 (115), as entirely noncontroversial, with some of the money sitting unused in accounts for two decades. Neutral experts have confirmed that the vast majority of the cutbacks would have zero programmatic effect.

But some longtime appropriators, including Senate Appropriations Chairman Richard Shelby (R-Ala.), are withholding support, even as most of their GOP colleagues flock behind Trump's first major attempt at deficit reduction to get a vote in Congress.

Some say they're skeptical of the administration's efforts to fast-track cuts to programs they aren't ready to kill, like rural infrastructure, clean energy and even a relatively new initiative that lets states use cash from unfinished earmarks projects.

"There's a lot of things there that don't make a lot of difference, but appropriators don't like rescissions, so we're going to have to think about that," Rep. John Carter (R-Texas), who oversees the Homeland Security bill, told POLITICO on Wednesday.

That initial resistance includes Sen. Lisa Murkowski — whose vote could help determine whether the bill passes the narrowly divided Senate. With Arizona Sen. John McCain's absence, Republicans have a 50 to 49 majority, and can't afford to lose a single GOP vote.

Murkowski (R-Alaska) said she isn't sold on the administration's proposal to cut $684 million from a clean energy loan guarantee program. "I want to make sure that if you take the funds from the account, you don't eliminate the program," the Interior-Environment Subcommittee chairwoman told reporters Thursday. "I don't want Title 17 programs eliminated. I want them reformed."

Rep. Mike Simpson (R-Idaho), who holds that position in the House, said Thursday he is "leaning no" on the proposal for the same reason. He said the clean energy program is "something I want to continue."

Shelby said he's concerned about cuts to the Appalachian Development Highway System. The White House has proposed $45.2 billion in cuts to that program, which the House matched in its bill unveiled Wednesday night.

"My state has benefited from that over the years," Shelby told reporters, noting that the bill could still see tweaks before it comes to a vote in the Senate. "I'm waiting to see what comes up first and where it comes up."

As a 24-year veteran of the Appropriations panel, Shelby is one of few sitting lawmakers to witness the last round of rescissions in 2000. And he said any cost-cutting proposal from 1600 Pennsylvania Avenue is likely to find at least a few critics on Capitol Hill.

"Since I've been up here — and I've been up here a few years — there's always some things in the rescissions package that a lot of members are committed to," Shelby said.

Meanwhile, Rep. Mario Diaz-Balart (R-Fla.) complained that the rescissions bill would roll back money that states could use for items such as infrastructure projects. That's because states can now access old cash that was earmarked for efforts that didn't get off the ground.

"Now, if you take it out, you're taking money out of the states' funds," the Transportation-HUD panel chairman said. "If you believe, like me, that infrastructure is a needed investment, I think that's problematic taking that away."

Appropriators are a fiercely independent breed on Capitol Hill, faced with a declining share of influence in the recent stop-and-go funding cycle. Now, they've been handed the largest-ever presidential rescissions request without a chance to vet it through their committees.

House GOP leaders are planning to bring the bill directly to the floor for a vote, as soon as next week. The Senate is expected to follow suit.

The Office of Management and Budget has said the $15.4 billion rescissions proposal would actually amount to less than $3 billion in spending cuts.

What's alarming to appropriators, though, is that the proposal would drain from Congress' ever-dwindling pool of "offsets," the equivalent of a rainy day fund for pending legislation.

The money that would be trimmed from the Children's Health Insurance Program, a federal fund for low-income families, for instance, has been used to help pay for the annual Labor-HHS-Education bill for years.

"Look, there's $5 billion of CHIP money that you can't spend. Why wouldn't you reclaim that money and put it back in the federal treasury?" asked Rep. Tom Cole, (R-Okla.), who oversees Labor-HHS-Education spending. "Or you can use it for an offset on something, which is normally what we've done in the past."

Cole is one of four appropriators to co-sponsor the package, along with Republican Reps. Tom Graves of Georgia, Kay Granger of Texas and Steve Womack of Arkansas. Of those, everyone but Womack is running for House Appropriations chairman this fall. And Womack is the leader of the House Budget Committee.

(The other contender for the House spending panel's gavel, Rep. Robert Aderholt (R-Ala.), was the first appropriator to go on record supporting the idea last month.)

"It's been carefully drawn, it doesn't violate our omnibus agreement, it doesn't violate our defense bill," Granger told POLITICO this week. Granger's panel oversees the Pentagon's budget, which wouldn't see a dollar cut under the White House's package.

Cole acknowledged that the dwindling pool of offsets would "probably" make it tougher for Congress to pay for some legislation down the road. But he said there are plenty of other ways to pay for something if leadership looked hard enough.

"In a $4 trillion budget, there's always something you can find to offset something else if it's really politically important enough to do," Cole said.

Anthony Adragna contributed to this report

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Democrats fear Pruitt's legal defense fund could create conflicts of interest Back

By Alex Guillén | 05/16/2018 04:38 PM EDT

EPA Administrator Scott Pruitt's newly formed legal defense fund has the embattled administrator's critics wondering whether companies he regulates will come to Pruitt's rescue behind the scenes.

Legal defense funds are subject to few formal rules, although any donations to help pay for Pruitt's lawyers would have to abide by existing ethics rules, including limitations on gifts from lobbyists or those with business before an official. While the Office of Government Ethics in September issued nonbinding guidance recommending that executive branch officials reject anonymous donations and consult with ethics officials before establishing such funds, critics say the system is ripe for potential abuse.

"You can see the conflicts," Sen. Tom Udall (D-N.M.) told reporters Wednesday, after pressing Pruitt on the legal defense fund during a congressional hearing. "A business is saying, 'I want this regulation to be repealed and so I'm going to give $100,000 to your legal defense fund.' That kind of activity just shouldn't be happening."

Experts say that even with those ethics boundaries, Pruitt will have significant leeway in deciding just how transparent the fund will be.

Craig Holman, a government affairs lobbyist at Public Citizen, compared the situation to the "Wild West."

"Legal defense funds in the executive branch can be set up any way the official prefers, including refusing to disclose the sources and amounts of donations," said Holman, who has petitioned OGE to create official rules for such funds.

In Pruitt's case, the fund must be set up as a private entity run by an independent third party and should not ask for donations from energy companies or lobbyists in order to comply with ethics laws, said Don Fox, a former general counsel and acting director for OGE. As for any other restrictions, he said, "OGE says, basically, 'We don't bless this; we're not telling you whether this good, bad or indifferent, but if you follow these guidelines, you should be OK.'"

Pruitt, who was an accomplished political fundraiser before joining the Trump administration, said the fund had been set up by his attorneys, not himself.

Pruitt told lawmakers on Wednesday that his attorney "who's done this for a number of years" has worked with the GAO "to make sure it's done properly."

He also said he would follow the advice of the White House Office of Legal Counsel on whether to accept anonymous donations, but he did promise not to personally solicit money from lobbyists or companies with business before EPA.

Asked by Sen. Chris Van Hollen (D-Md.) whether he would commit "not to accept donations from lobbyists or corporations that have business before the EPA," Pruitt replied, "Absolutely," although he then amended that statement.

"Let me clarify something. I don't accept the donations; I don't solicit donations. That's done by attorneys and others," Pruitt told the Maryland Democrat at Wednesday's hearing before a Senate Appropriations subcommittee. Pruitt said he would follow the advice of GAO and the White House regarding whether to accept anonymous donations.

As a rising star attorney general in Oklahoma several years ago, Pruitt raised millions for his own campaigns and outside conservative groups. Pruitt helped land millions of dollars in donations from the energy industry to the Republican Attorneys General Association, where he served several years as chair and an executive board member.

Major donors to RAGA during that time included Koch Industries and Devon Energy, an Oklahoma-based oil and gas company with close ties to Pruitt.

Pruitt later chaired the Rule of Law Defense Fund, but that group is not required to disclose its donors.

He also created a leadership PAC and a super PAC to promote his interests. Each one had raised about $45,000 but gave that money away and shut down once he was nominated to run EPA.

Pruitt did not specify which attorney set up his fund. The Washington Post on Wednesday reported it is run by Cleta Mitchell, an attorney at Foley & Lardner.

Mitchell did not answer questions from POLITICO about the fund.

"I do not respond to questions from reporters about any legal matters in which I may or may not be involved," Mitchell wrote in an email. "Administrator Pruitt has been a friend and client for a number of years."

Mitchell was a Democrat in Oklahoma's House of Representatives from 1976 to 1984, but her later law practice focused on representing conservatives, including Sen. Jim Inhofe (R-Okla.). She is a former board member of the National Rifle Association and the American Conservative Union, which runs the annual conservative confab known as "CPAC."

Mitchell has come to Pruitt's defense on Twitter in recent months.

On April 6, shortly after The New York Times reported that Pruitt had removed or reassigned career and political officials who questioned his actions, Mitchell tweeted: "NYT is outraged that Scott Pruitt moved EPA employees who fought his initiatives. That's exactly what we WANT him to do."

She tweeted a few days later that Sen. Sheldon Whitehouse (D-R.I.) "and his crazy environmentalist cronies have FED the hostility against Pruitt. Pray for Pruitt's safety."

Ben Lefebvre, Annie Snider and Anthony Adragna contributed to this report.

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How Trump's climate skeptics are changing the country Back

By Emily Holden | 03/07/2018 05:02 AM EDT

President Donald Trump is filling the upper ranks of his administration with appointees who share his disbelief in the scientific evidence for climate change — giving them an opportunity to impose their views on policies ranging from disaster planning to national security to housing standards.

At the Interior Department, decisions about Pacific island territories threatened by rising seas are in the hands of an assistant secretary who has criticized "climate alarmists" for "once again predicting the end of the world as we know it." Agriculture Secretary Sonny Perdue's top advisers include a former talk radio host who has dismissed much climate research as "junk science." Trump's nominee to head research and technology at the Department of Transportation claimed three years ago that global warming had "stopped" — a position at sharp odds with the findings of federal agencies like NASA.

Trump has chosen at least 20 like-minded people to serve as agency leaders and advisers, according to a POLITICO review of his appointees' past statements on climate science. And they are already having an impact in abandoning former President Barack Obama's attempt to help unite the world against the threat of rising sea levels, worsening storms and spreading droughts.

[Sneak preview for Pro subscribers: Trump's climate science doubters]

Most famously, the president and his team have scrubbed mentions of climate change from government websites, kicked scientists off advisory boards, repudiated the Obama administration's greenhouse gas regulations and made the U.S. the only nation on Earth to reject the 2015 Paris agreement on global warming.

More quietly, Trump's White House excluded rising temperatures from the list of threats in its December national security strategy, contradicting the approach of both the Obama and George W. Bush administrations. Last year, just before Hurricane Harvey drowned Houston, the White House rescinded requirements that projects built with federal dollars take into account the way warming temperatures might intensify extreme weather.

People worried about the consequences of climate change say a government that denies the problem is courting danger.

"The analogy could be if somebody's got a heart problem or high cholesterol, you take medicine that helps manage that so you can avoid a heart attack," said Ana Unruh Cohen, the government affairs director at the Natural Resources Defense Council. "Trump taking that away, saying, 'Forget it, I don't believe I have high cholesterol,' is setting up the country for a heart attack."

Aparna Mathur, a resident scholar in economic policy at the conservative American Enterprise Institute, found the trend worrying as well.

Many administration officials "don't seem to believe climate change is real, or if they believe climate change is real, there's this sort of attitude that there's not much to do about it or it's not caused by human actions," said Mathur, whose AEI colleagues also include people who question the extent of man-made climate change. As a result, she said, the U.S. is falling behind countries that are taking action on the problem.

The doubts are coming from both prominent and little-known Trump appointees, in ways both obscure and subtle.

Some have expressed doubt that the Earth is warming at all, speculated that the trend might be good for humans, or said it's just impossible to know how much of a role humans and their pollution are playing. All these statements fly in the face of findings by the government's own research agencies and the vast majority of climate scientists.

"There are scientists that think lots of different things about climate change," then-Rep. Mike Pompeo (R-Kan.), now Trump's CIA director, said on C-SPAN in 2013. "There's some who think we're warming, there's some who think we're cooling, there's some who think that the last 16 years have shown a pretty stable climate environment." Pompeo dodged the issue in his confirmation hearing last year, saying he would "prefer today not to get into the details of the climate debate and science."

When he was running for president, HUD Secretary Ben Carson scoffed at the idea that strong evidence for human-caused climate change even exists. "I know there are a lot of people who say 'overwhelming science,' but then when you ask them to show the overwhelming science they never can show it," he told the San Francisco Chronicle in 2015.

Few have been as publicly outspoken on the issue as Trump, who more than once has dismissed human-caused climate change as a "hoax" and claimed in January that polar ice isn't melting.

The White House sought to strike a somewhat more moderate tone in a statement to POLITICO on Monday, which said that "the climate has changed and is always changing. The Administration supports rigorous scientific analysis and debate." The statement from principal deputy press secretary Raj Shah added that "the development of modern and efficient infrastructure ... will reduce emissions and enable us to address future risks, including climate related risks."

Some of the administration's climate skeptics have already come and gone.

Former HHS Secretary Tom Price, who had criticized the "allegedly 'settled science' of global warming" as a member of Congress, resigned in September amid criticism of his expensive travels on government and private planes. Kathleen Hartnett White, Trump's pick to head the White House Council on Environmental Quality, withdrew her nomination earlier this year after she stirred criticism with a long list of controversial statements , including calling the human role in climate change "very uncertain."

Another unsuccessful nominee, former talk radio host and political science professor Sam Clovis, had to pull out of the running to be USDA's chief scientist after critics noted that he has no science credentials — but he remains a top adviser to Perdue. Clovis dismissed much climate research as "junk science" in a 2014 interview, adding that "a lot of this global warming ... is really about income redistribution from rich nations that are industrialized to nations that are not."

Brent Fewell, a conservative environmental lawyer who was an EPA water official under Bush, suggested that some of these officials may privately acknowledge that man-made climate change is real. But he added: "A lot

of people on the political right are uninformed about the issue. For whatever reason, it's a lot easier to simply agree with the prominent voices in the political party."

The upshot is the same, however: a 180-degree reversal from Obama's efforts to make the U.S. a leader in addressing the causes and consequences of a warming planet.

The EPA is leading the charge by withdrawing or weakening a host of climate regulations, including a 2015 rule that would have sped the electric power industry's shift away from coal-fired energy. Trump has also approved tariffs for solar panel imports, which will make it harder for green energy to compete with fossil fuels. Agencies have sought to cancel rules meant to limit the oil and gas industry's methane pollution — another major greenhouse gas source — and are reconsidering tougher standards for vehicles, too.

The Energy Department has proposed regulatory changes to prop up coal plants that can't compete in the market, while the White House is seeking buyers for U.S. coal and gas exports.

When Trump's critics seek to challenge these actions in court, the government's defense will be run by the Justice Department — an agency whose leader, Attorney General Jeff Sessions, said during a 2015 Senate hearing that carbon dioxide is "really not a pollutant."

"It's a plant food, and it doesn't harm anybody except that it might include temperature increases," Sessions said.

Some agencies are still continuing to study climate change and factor their findings into their policy decisions. But even there, career staffers may not talk about their work as openly as they once did, and the agencies seldom showcase it the way they did during the Obama years.

Much of the alarm among Trump's critics focuses on EPA, which has replaced dozens of scientists on its key advisory boards with industry or state representatives, and has found other ways to keep researchers from contradicting the administration's message. Last fall, the agency canceled an appearance by three EPA scientists scheduled to speak about climate change at a Narragansett Bay conference . Both EPA and the Energy Department have given extra scrutiny to grant proposals with the words "climate change," and in the case of EPA, it has put a political appointee in charge of signing off on them, The Washington Post has reported.

All this is in line with the public statements of EPA Administrator Scott Pruitt, who has suggested that global warming might be a good thing and has spoken about holding a public debate on whether climate change is real.

"Right out of the gate ... the administration took any and all mention of climate change off of the White House website," said Jacob Carter, a research scientist who has been tracking the administration's treatment of science for the Union of Concerned Scientists. "It seems like the administration is really trying to undo a lot of the scientific process as a whole and get experts out of the way."

The Environmental Data and Governance Initiative, which has studied the purging and rewording of climate-related documents on government websites, reported at the end of 2017 that it had found a "significant loss of public access to information about climate change."

The State Department's website took down links related to the Paris climate agreement, EPA removed a student's guide to climate change, and the Energy Department got rid of the words "clean energy" on a page with information for investors and businesses looking for projects with national laboratories.

The Interior Department's Bureau of Land Management, which oversees energy development on federal land, cut text about the effects of climate change. Some of the resources are still technically available in archives or in new locations, but they are harder to find because the government sites don't directly link to them, the Environmental Data and Governance Initiative says.

"It's not alarming the public because it's very hard to see each incremental thing," said Andrew Bergman, a co-author of the report.

Some Trump appointees have downplayed the idea that agency leaders' personal views about climate change are critical to making policy, suggesting they can still respond to global warming's effects without addressing why it's happening.

"We continue to take seriously climate change — not the cause of it, but the things that we observe," Tom Bossert, the president's homeland security adviser, told reporters after last year's spree of catastrophic hurricanes that ravaged Houston, Puerto Rico and the Virgin Islands.

Sarah Hunt, who works in energy policy at the conservative American Legislative Exchange Council, said that "policymaker views on climate science needn't have any bearing on their support for conservative clean energy policies that spur the innovation we need to reduce emissions and promote environmental stewardship while we grow our economy."

But Trump's actions have reflected his views on the science. For example, one of his early executive orders in March 2017 eliminated a number of ways agencies had been required to consider climate change, including in environmental reviews for infrastructure projects.

Because so many of his appointees have questioned the conclusions of climate scientists, they are jettisoning climate change from routine processes. Those include EPA's refusal to consider the global monetary benefits of curbing rising temperatures when it rolled back Obama-era rules for the power sector.

Still, some agencies have continued to issue major reports that warn that climate change is a real and growing problem — even as the president's staffers push the message that the science is uncertain.

In November, the government's 13-agency National Climate Assessment concluded that humans have pushed global temperatures to their highest level in modern times. In January, NASA published data showing that last year was the second-warmest on record, and noted that temperature rises are "driven largely by increased carbon dioxide and other human-made emissions into the atmosphere."

Trump's nominee to run the space agency, Rep. Jim Bridenstine (R-Okla.), criticized "climate change alarmists" on the House floor in 2013 and claimed that "global temperatures stopped rising 10 years ago." (In fact, they haven't.) At his confirmation hearing last year, he acknowledged that humans are a cause of climate change but wouldn't call them the main cause.

"That is a question that I do not have an answer to," he said.

To view online click here.

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House panel green-lights Commerce-Justice-Science bill Back

By Hugh T. Ferguson and Sarah Ferris | 05/17/2018 04:19 PM EDT

The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill, marking its fifth completed bill of the spending cycle. The vote was 32-19, along party lines.

In a rare bipartisan moment in the five-hour markup, lawmakers agreed to add a provision to uphold sanctions against the Chinese phone-maker ZTE, just days after President Trump declared he is seeking to lessen the penalties.

Another bipartisan addition would protect medical marijuana in states where it's already legal — language that was skipped over in last year's markup but adopted this year with barely an objection.

The fiscal 2019 measure would provide $62.5 billion for the wide-ranging Commerce-Justice-Science bill, which funds federal law enforcement, NASA and the National Science Foundation, a $2.9 billion bump above current levels.

The bill would fund the Department of Justice at $30.7 billion, an increase of $793 million from fiscal 2018. Within that, the FBI's budget would dip slightly, although it is still $400 million more than the White House request.

The budget for the U.S. Census would swell to $4.8 billion, nearly double the current levels, as officials ramp up for the 2020 survey.

NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request.

Another $447 million would go toward the national fight against opioid addiction, the same amount in this year's omnibus, H.R. 1625 (115).

House Democrats, along with a pair of Republicans, offered 18 amendments. Many were targeting specific riders that they viewed as partisan threats to the measure's passage.

The panel also unanimously backed a manager's amendment from subcommittee Chairman John Culberson (R-Texas). The amendment contained a number of provisions that each side had agreed upon, according to Culberson and Rep. José Serrano (D-N.Y.) ranking member of the subcommittee.

Amendments included:

— Barbara Lee (D-Calif.) amendment that would strip the measure of three firearm related provisions with the intent to reduce gun violence, rejected 20-31.

— Matt Cartwright (D-Pa.) amendment that would increase funding for the NOAA climate research program, withdrawn.

— Nita Lowey (D-N.Y.) amendment that would prevent individuals from purchasing a firearm by giving the attorney general the authority to deny the sale of a firearm to an individual buyer believed to be aiding in acts of terrorism, rejected 20-31.

— Lucille Roybal-Allard (D-Calif.) amendment that would prohibit the use of funds to prosecute immigrants who have illegally entered the U.S. seeking asylum unless they have committed serious criminal acts or present a danger to the U.S., rejected.

— David Price (D-N.C.) amendment related to eviction proceedings with competitive grant funding for legal services in high eviction areas, rejected 22-28.

— Dave Joyce (R-Ohio) amendment related to protections for state medical marijuana laws, adopted on voice vote.

— Dutch Ruppersberger (D-Md.) amendment related to moving the FBI into a new headquarters, withdrawn.

— Betty McCollum (D-Minn.) and Tom Cole (R-Okla.) amendment related to funding increase for tribal nations under the Crime Victims Fund, adopted on voice vote.

— Derek Kilmer (D-Wash.) amendment related to increasing funding for coastal resilience programs at NOAA, withdrawn.

— Debbie Wasserman Schultz (D-Fla.) amendment related to restoring stricter reporting rules for certain semi-automatic guns, rejected by voice vote.

— Henry Cuellar (D-Texas) amendment related to protecting land by limiting the government's eminent domain powers when it comes to building a border wall, rejected by voice vote.

— Ruppersberger amendment related to enforcing sanctions against ZTE, adopted by voice vote.

— Lowey amendment protecting the special counsel at the Department of Justice, rejected 23 to 27.

— Grace Meng (D-N.Y.) amendment related to increasing funding for juvenile delinquency prevention programs, withdrawn.

— Serrano amendment related to the new citizenship question on the 2020 U.S. Census, rejected by voice vote.

— Ruppersberger amendment related to federal grants tackling contraband cellphone use in prisons.

— Andy Harris (R-Md.) amendment related to DEA research on medical risks and benefits of marijuana, withdrawn.

— Ruppersberger amendment related to NASA satellite program, withdrawn.

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NATO chief thanks Trump for leadership on military spending Back

By Eli Okun | 05/17/2018 03:26 PM EDT

NATO Secretary-General Jens Stoltenberg praised President Donald Trump on Thursday for pushing countries in the alliance to boost their defense spending, an issue that has driven a wedge between Trump and Europe before.

"Let me thank you for the leadership you show on the issue of defense spending because it is very important that we all contribute more to our shared security, and it is really having an impact because, as you said, allies are now spending more on defense," Stoltenberg said while taking reporters' questions after the leaders met at the White House. "All allies are increasing their defense budgets."

"Do you give me credit for that?" Trump pressed.

"You have helped to do that," Stoltenberg said.

It was a notable moment for a U.S.-NATO relationship that has sometimes seemed on shaky ground during the Trump administration.

A minority of NATO's members — including the U.S. — meet the alliance's nonbinding guideline for each country to spend at least 2 percent of its GDP on defense.

Other American presidents have pressed their NATO allies to increase military budgets. But the issue has become a particular flashpoint for Trump, who is often skeptical of international alliances or deals that he deems unfair to the U.S.

"Together we've increased and really raised a lot of money from countries that weren't paying, or weren't paying a fair share," Trump said on Thursday. "We have a little ways to go, but many billions of dollars of additional money has been raised."

Stoltenberg later told the president: "Your leadership on defense spending has really helped to make a difference."

Trump noted that he thought the alliance should increase the standard to 4 percent.

Last year, Trump reversed his previous dismissals of the alliance and said he no longer considered NATO "obsolete." But he's continued to raise concerns about spending — including to Chancellor Angela Merkel of Germany last month.

Trump again singled out Germany on Thursday, calling it "a very big beneficiary" that "must demonstrate leadership."

And though Trump said the alliance needed to improve its counterterrorism capabilities, he repeated that the U.S. was committed to NATO's Article 5.

Early in his administration, Trump scared European allies by deciding on the fly to scrap a public affirmation of Article 5, the longstanding lynchpin of the alliance that guarantees the countries' commitment to mutual defense. But by June 2017, he committed to the article.

Though the president's decision last week to abandon the Iran nuclear deal angered European allies, Secretary of State Mike Pompeo, who took office last month, has made a more positive impression on NATO so far.

The leaders' meeting came ahead of a NATO summit in July.

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EPA watchdog: Investigator says he did not socialize with Pruitt security chief Back

By Alex Guillén | 04/13/2018 05:46 PM EDT

A top investigator at EPA's Office of Inspector General is disputing a report that he is friends with the head of Administrator Scott Pruitt's protective detail, according to a spokeswoman for the internal watchdog.

The New York Times reported Thursday that Patrick Sullivan, the assistant IG in charge of investigations, has been seen drinking beers at a bar across the street from EPA's headquarters with Pasquale "Nino" Perrotta, who last year became the head of Pruitt's security detail after his predecessor was removed.

Citing that report, a left-leaning nonprofit group on Friday requested an investigation from a council of federal inspectors general. But Sullivan says the Times got it wrong.

Sullivan "confirmed that he has never had drinks with Mr. Perrotta anywhere or at any time. He has never been to the Elephant and Castle with Mr. Perrotta," IG spokeswoman Tia Elbaum said in an email Friday.

While they had both previously worked for the Secret Service, Sullivan and Perrotta did not know one another until Sullivan began working for the EPA IG in 2011, according to Elbaum. "They are professional colleagues and friendly, but do not socialize outside of work," she said. (Perrotta, who has become a key figure in some of the controversies surrounding Pruitt, arrived at EPA in 2004, and initially worked at the OIG but moved to the security detail before Sullivan was hired.)

Another spokesman for the OIG said they have not yet asked for a retraction but may do so in the future.

A spokesperson for the Times said the paper stands by its story.

The watchdog group Citizens for Responsibility and Ethics in Washington on Friday asked for an investigation into their relationship.

The alleged socialization is "conduct that may undermine the independence or integrity reasonably expected of Mr. Sullivan," wrote CREW in a letter to officials at the independent Council of the Inspectors General on Integrity and Efficiency.

The Times did not specify the source or sources who claimed to have spotted Sullivan and Perrotta having drinks, but its original report said a spokesman for EPA's inspector general had disputed that the two men socialized outside of work. The story does not appear to have been updated since it was first published.

To view online click here.

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Message

From: Morning Energy [morningenergy@politico.com]
Sent: 5/18/2018 2:08:40 PM
To: Jackson, Ryan [jackson.ryan@epa.gov]
Subject: POLITICO's Morning Energy, presented by Chevron: Another House WOTUS vote ... maybe — Trump signs efficiency EO — More calls for release of chemical safety study

By Kelsey Tamborrino | 05/18/2018 10:00 AM EDT

With help from Anthony Adragna and Annie Snider

ANOTHER HOUSE WOTUS VOTE ... MAYBE: The House is scheduled to vote today on an amendment to the farm bill, H.R. 2 (115), from Indiana Republican Rep. Jim Banks that would repeal the Obama administration's Waters of the U.S. rule. Provisions targeting the rule, which is deeply reviled in farm country, have been approved repeatedly, including when attached to appropriations measures, only to be stripped in the end. But WOTUS opponents keep hoping that the stars will align for them on a must-pass bill.

Banks touted the amendment on a local radio show Thursday. "With the farm bill on the floor, I thought, 'Well, this is a natural place to fully and permanently repeal WOTUS once and for all," he said, adding that groups like Heritage Action, the U.S. Chamber of Commerce and Club for Growth, have backed his amendment. "This is a rule that scares not just farmers, but a lot of property owners and developers and people who understand that this is federal government going way too far," he added.

The farm bill may not be that measure, though — at least not right now. As Helena Bottemiller Evich, Liz Crampton and Rachael Bade report, the House Freedom Caucus is threatening to scuttle the bill unless a vote on conservative immigration legislation is held first. House GOP leaders maintain lawmakers will still vote on the legislation today, despite the threat.

Separately, 40 environmental groups — including the League of Conservation Voters, Earthjustice and the Sierra Club — signed onto a letter urging House lawmakers to reject the amendment. "It's really this simple: a vote for this rider is a vote against clean water, a vote to expose even more communities to unsafe drinking water, a vote to limit the scope of the Clean Water Act, and a vote to allow polluters to destroy our precious waterways," they write.

The House is scheduled to meet at 9 a.m. for legislative business, with first and last votes expected between 10:30 a.m. and 11:30 a.m. See the full list of amendments here.

GET A WRDA IN EDGEWISE: Meanwhile, the House Transportation Committee will release its own Water Resources Development Act today, the committee's chairman said. The bill is expected to differ significantly from the Senate's version that will be marked up Tuesday, Pro's Annie Snider and Anthony Adragna report, but it does have the support of the committee's ranking member Peter DeFazio and the top Democrat and Republican on the Water Resources and Environment Subcommittee. GOP Rep. Garret Graves, the subcommittee chairman, said the House measure will include language relating to one of his top priorities: moving the Army Corps of Engineers out of the Defense Department. On the Senate side, both Democrats and Republicans have been wary of that idea. However, Graves indicated the House bill will not make that move immediate.

WE MADE IT TO FRIDAY! I'm your host Kelsey Tamborrino. Turns out there are a few different ways to answer yesterday's trivia question. But I'm giving the win to LCV's Gene Karpinski, who was the first to identify Rock Creek Park, authorized in 1890, as what the National Park Service calls the third national park to

be designated by the federal government. For today, a related question: William Henry Jackson was the first person to photograph Yellowstone. What monument is home to the largest single holding of his paintings? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy, and @POLITICOPro.

TRUMP SIGNS EFFICIENCY EO : President Donald Trump signed an executive order late Thursday to prioritize efficiency in the government. The order calls on agencies to "prioritize actions that reduce waste, cut costs, enhance the resilience of Federal infrastructure and operations, and enable more effective accomplishment of its mission." It focuses on increasing efficiency of federal buildings and vehicles in a cost-effective manner. The president also directed the Council on Environmental Quality and the Office of Management and Budget to streamline energy and environmental requirements, in a simplified and accountable manner. Last year, the White House said, agencies spent more than $6 billion on energy for buildings and $635 million on water. Within 90 days, the Agriculture and Energy secretaries and the administrators of EPA and General Services, are tasked with reviewing relevant established government-wide guidance and in conjunction with CEQ, must "develop a plan and proposed timeline to modify, replace, or rescind such guidance, as necessary."

But the order also notably rescinds an Obama-era order from March 2015 that focused on sustainability, requiring agencies to slash its greenhouse gas emissions and address climate change. That EO set a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years. Trump's order makes no mention of climate change or emissions reductions. Instead it calls on agencies to track and report greenhouse gas emissions. Read the order here.

SENATE'S 'BIG FOUR' ON NUCLEAR WASTE PLAN MEETING: A bipartisan group of four senior senators are planning to get together in hopes of launching a new push on nuclear waste legislation, according to Sens. Lisa Murkowski and Lamar Alexander. "Our staffs have been working, but I don't know if a date has been set," Murkowski, chairman of the Energy Committee, told ME. Their Democratic counterparts at the meeting would be Sens. Dianne Feinstein and Maria Cantwell. The planned meeting comes after the House passed its own broad nuclear waste overhaul that would move the Yucca Mountain repository forward.

SIMPSON STILL 'LEANING NO' ON RESCISSIONS: Rep. Mike Simpson, who chairs an Appropriations panel responsible for DOE funding, says he's "leaning no" on a proposed list of $15.4 billion in cutbacks from the administration but plans to continue his review of it. "I want to look at the loan guarantees," he told reporters. "Most of them are probably going to be OK. There some that might not be." Remember Simpson's one of several senior Appropriators who've expressed reservations about the package.

BARRASSO STILL CONCERNED ABOUT PRUITT: Senate EPW Chairman John Barrasso says he isn't giving EPA Administrator Scott Pruitt a free pass even as he remains non-committal about when he'll haul the embattled EPA chief before his committee. "I still have lots of concerns with regards to spending issues," he told reporters. "I continue to send and ask questions."

ALL IN THE TIMING: Depending on when Pruitt created his legal defense fund, onlookers may have to wait another year to see who donated. As E&E News reports, the embattled EPA chief is required to report gifts received on his public financial disclosure report, which would include contributions to the legal defense fund established for his benefit, according to guidance on the Office of Government Ethics' website. But those reports are only filed once a year, meaning if Pruitt's defense fund was created this year, he'd report it for the 2018 calendar year, which isn't required to be filed until May 2019 at the earliest. Of course, that means if Pruitt created the fund in the 2017 calendar year, it would be in the financial disclosure report that Pruitt recently got an extension to file. Read more.

BRIDENSTINE: 'GREENHOUSE GAS IS WARMING THE PLANET': NASA's Jim Bridenstine held his first town hall as administrator Thursday, where he clarified his stance on climate change. He said his position

on the issue has "evolved," and he described the impact of tornadoes in his home state. "I don't deny the consensus that the climate is changing, in fact I fully believe and know that the climate is changing," Bridenstine said. "I also know that we human beings are contributing to it in a major way." The former Oklahoma lawmaker, who was recently confirmed to the agency, faced previous criticism from Democrats over his denial that climate change is caused by humans. During Thursday's address, Bridenstine instead praised the work of NASA and defined carbon dioxide as a greenhouse gas. "We're putting it to the atmosphere in volumes that we haven't seen and that greenhouse gas is warming the planet," he said. "That is absolutely happening and we are responsible for it." Watch his remarks here.

MORE CALLS FOR RELEASE OF CHEMICAL SAFETY STUDY: Calls continue to mount for the Trump administration to release a hot-button assessment of the chemicals PFOA and PFOS that POLITICO reported Monday was described as a "public relations nightmare" by a White House official. New York Democratic Rep. Sean Patrick Maloney will add his voice to the chorus with a letter to Pruitt today. Maloney's Hudson River Valley district includes Newburgh, N.Y., where the chemicals have leached from the nearby Stewart Air National Guard Base. State-funded blood tests have found that residents there have more than three times the amount of PFOS in their blood than the average American.

HOUSE APPROPRIATIONS SCIENCE BILL ADVANCES: The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill Thursday on a party-line vote of 32-19. The fiscal 2019 measure would increase spending for federal law enforcement, NASA and the National Science Foundation by $2.9 billion to a total of $62.5 billion, Pro's Hugh Ferguson and Sarah Ferris report. NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request. Among the 18 amendments offered, two Democrat-offered NOAA-related ones were withdrawn. One was related to increasing funding for coastal resilience programs at NOAA, and another would increase funding for the NOAA climate research program.

Speaking of NOAA: The agency found April 2018 marked the 400th consecutive month with temperatures above average. Additionally, NOAA said the average global temperature for April was 1.49 degrees F above the 20th-century average of 56.7 degrees — the third highest for April in the 139-year record, with 9 out of the 10 warmest Aprils occurring since 2005.

CLIMATE CAUCUS WELCOMES FIVE MEMBERS: The Climate Solutions Caucus welcomed five new members to its ranks on Thursday: Reps. Erik Philip Paulsen, Tom MacArthur, Eliot Engel, Peter Roskam and Ron Kind. The additions bring the bipartisan caucus' total to 78 members.

CORPS GRID RESTORATION ENDS TODAY: At the direction of the CEO of the Puerto Rican power company PREPA and the Energy Unified Command Group, FEMA said that as of today the Army Corps of Engineers will no longer provide line restoration work for the power authority. Instead, PREPA will oversee its contractors and the remaining work in grid restoration. PREPA reports 98.86 percent of pre-storm customers have had their power restored, with 16,723 remaining without power, as of Wednesday.

But FEMA said Thursday it had approved the extension of an Army Corps mission assignment that allows for the lease, generation and maintenance of three "mega generators" until PREPA completes its purchase of the generators.

NATURAL GAS AND NATO: Although it was not immediately clear how, Trump said Thursday gas would play a role in upcoming NATO talks. The president remarked on Germany's relationship with Russia during his meeting with Secretary-General Jens Stoltenberg, who praised Trump for pushing countries in the alliance to boost their defense spending. In his remarks, Trump specifically called out Germany for its "longstanding shortfall in defense contributions." Trump called the member nation "a very big beneficiary" that "must demonstrate leadership." He added, "they're buying massive amounts of gas from Russia and paying billions

and billions of dollars. So I think that's something we'll be discussing later and we'll be discussing that at our meeting, and probably long before the meeting." The leaders' meeting came ahead of a NATO summit in July.

Meanwhile, The Wall Street Journal reported on Thursday that U.S. and European officials said Trump told German Chancellor Angela Merkel in April that Germany should drop support for Nord Stream 2, an offshore pipeline that would bring gas directly from Russia via the Baltic Sea. This would be in exchange for the U.S. starting talks with the European Union on a new trade deal.

DEPARTMENT OF CORRECTIONS: The New York Times set the record straight last night, issuing a correction to its story from April 13 that said the former head of Pruitt's security detail, Pasquale "Nino" Perrotta, had met for drinks with an an official from the EPA inspector general's office. That report had raised concerns in some quarters about the independence of the IG investigator.

The story, the paper said, "erroneously included Mr. Perrotta among those who gathered for beers at an event at the Elephant and Castle in Washington that was attended by Patrick Sullivan, the assistant inspector general who oversees investigations at the E.P.A. Mr. Sullivan said that Mr. Perrotta had been invited but did not attend that gathering and that he has never met for drinks with Mr. Perrotta, though he acknowledged that the two men met for lunch several months later at another restaurant near the E.P.A. headquarters."

MAIL CALL! Democratic Sens. Ed Markey, Sheldon Whitehouse and Tom Carper , members of the EPW Committee, called on EPA to publicly release a health assessment on the effects of formaldehyde exposure. They cite an exchange between Markey and Pruitt during his January appearance before the committee where Pruitt said he'd get back to the senator on the progress of the report. "Unfortunately, it appears that the agency may be succumbing to pressure from industry in its attempt to delay or block the publication of the formaldehyde health assessment," they write. Read it here.

CONGRATS ARE IN ORDER: Barrasso congratulated Wyoming Gov. Matt Mead in a letter this week on the dedication of the state's Integrated Test Center near Gillette. The carbon capture research facility, dedicated Wednesday, is a testing space off the back of the operating coal power plant. Five Carbon XPrize finalists — U.S., Canada, India, China and Scotland — will head to the site to put their concepts to capture CO2 from the power plant and convert it to a marketable product to the test. In his letter, Barrasso called the ITC "an important resource for Wyoming's economy." Read it here.

ROCKET TO THE SUN: House Science Chairman Lamar Smith said Thursday he submitted the names of committee members and staff to be placed aboard the Parker Solar Probe on its "mission to touch the Sun." NASA opened up the opportunity to the public to submit names to be stored on a memory card and installed on the probe before it launches this summer. "When I came across NASA's unique offer, I thought this would be a perfect and light-hearted opportunity to carve the names of the members and staff in history," Smith said in a statement.

SEE IT: Electricity generation will vary widely over the coming decades, according to U.S. Energy Information Administration's projections. Pro's DataPoint team breaks down the numbers in a graphic here. Want to add DataPoint to your Pro account? Learn more.

QUICK HITS

— Florida congressional delegation gives thumbs-down to offshore drilling, McClatchy.

— Republican lawmaker: Rocks tumbling into ocean causing sea level rise, E&E News.

— Emails show Interior expected to learn nothing from public input on Bears Ears review, Huffington Post.

— Zinke moves to protect critical minerals from foreign threats, Washington Examiner.

— Zinke tells greens he'll make 'grand pivot' to conservation, E&E News.

— Will Trump's pick to run EPA in California show up for work? Los Angeles Times.

THAT'S ALL FOR ME!

To view online:
https://www.politico.com/newsletters/morning-energy/2018/05/18/another-house-wotus-vote-maybe-222339

Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 5/18/2018 9:49:27 AM
To: Jackson, Ryan [jackson.ryan@epa.gov]
Subject: Morning Energy, presented by Chevron: Another House WOTUS vote ... maybe — Trump signs efficiency EO — More calls for release of chemical safety study

By Kelsey Tamborrino | 05/18/2018 05:43 AM EDT

With help from Anthony Adragna and Annie Snider

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Separately, 40 environmental groups — including the League of Conservation Voters, Earthjustice and the Sierra Club — signed onto a letter urging House lawmakers to reject the amendment. "It's really this simple: a vote for this rider is a vote against clean water, a vote to expose even more communities to unsafe drinking water, a vote to limit the scope of the Clean Water Act, and a vote to allow polluters to destroy our precious waterways," they write.

The House is scheduled to meet at 9 a.m. for legislative business, with first and last votes expected between 10:30 a.m. and 11:30 a.m. See the full list of amendments here.

GET A WRDA IN EDGEWISE: Meanwhile, the House Transportation Committee will release its own Water Resources Development Act today, the committee's chairman said. The bill is expected to differ significantly from the Senate's version that will be marked up Tuesday, Pro's Annie Snider and Anthony Adragna report, but it does have the support of the committee's ranking member Peter DeFazio and the top Democrat and Republican on the Water Resources and Environment Subcommittee. GOP Rep. Garret Graves, the subcommittee chairman, said the House measure will include language relating to one of his top priorities: moving the Army Corps of Engineers out of the Defense Department. On the Senate side, both Democrats and Republicans have been wary of that idea. However, Graves indicated the House bill will not make that move immediate.

WE MADE IT TO FRIDAY! I'm your host Kelsey Tamborrino. Turns out there are a few different ways to answer yesterday's trivia question. But I'm giving the win to LCV's Gene Karpinski, who was the first to identify Rock Creek Park, authorized in 1890, as what the National Park Service calls the third national park to

be designated by the federal government. For today, a related question: William Henry Jackson was the first person to photograph Yellowstone. What monument is home to the largest single holding of his paintings? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy, and @POLITICOPro.

TRUMP SIGNS EFFICIENCY EO : President Donald Trump signed an executive order late Thursday to prioritize efficiency in the government. The order calls on agencies to "prioritize actions that reduce waste, cut costs, enhance the resilience of Federal infrastructure and operations, and enable more effective accomplishment of its mission." It focuses on increasing efficiency of federal buildings and vehicles in a cost-effective manner. The president also directed the Council on Environmental Quality and the Office of Management and Budget to streamline energy and environmental requirements, in a simplified and accountable manner. Last year, the White House said, agencies spent more than $6 billion on energy for buildings and $635 million on water. Within 90 days, the Agriculture and Energy secretaries and the administrators of EPA and General Services, are tasked with reviewing relevant established government-wide guidance and in conjunction with CEQ, must "develop a plan and proposed timeline to modify, replace, or rescind such guidance, as necessary."

But the order also notably rescinds an Obama-era order from March 2015 that focused on sustainability, requiring agencies to slash its greenhouse gas emissions and address climate change. That EO set a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years. Trump's order makes no mention of climate change or emissions reductions. Instead it calls on agencies to track and report greenhouse gas emissions. Read the order here.

SENATE'S 'BIG FOUR' ON NUCLEAR WASTE PLAN MEETING: A bipartisan group of four senior senators are planning to get together in hopes of launching a new push on nuclear waste legislation, according to Sens. Lisa Murkowski and Lamar Alexander. "Our staffs have been working, but I don't know if a date has been set," Murkowski, chairman of the Energy Committee, told ME. Their Democratic counterparts at the meeting would be Sens. Dianne Feinstein and Maria Cantwell. The planned meeting comes after the House passed its own broad nuclear waste overhaul that would move the Yucca Mountain repository forward.

SIMPSON STILL 'LEANING NO' ON RESCISSIONS: Rep. Mike Simpson, who chairs an Appropriations panel responsible for DOE funding, says he's "leaning no" on a proposed list of $15.4 billion in cutbacks from the administration but plans to continue his review of it. "I want to look at the loan guarantees," he told reporters. "Most of them are probably going to be OK. There some that might not be." Remember Simpson's one of several senior Appropriators who've expressed reservations about the package.

BARRASSO STILL CONCERNED ABOUT PRUITT: Senate EPW Chairman John Barrasso says he isn't giving EPA Administrator Scott Pruitt a free pass even as he remains non-committal about when he'll haul the embattled EPA chief before his committee. "I still have lots of concerns with regards to spending issues," he told reporters. "I continue to send and ask questions."

ALL IN THE TIMING: Depending on when Pruitt created his legal defense fund, onlookers may have to wait another year to see who donated. As E&E News reports, the embattled EPA chief is required to report gifts received on his public financial disclosure report, which would include contributions to the legal defense fund established for his benefit, according to guidance on the Office of Government Ethics' website. But those reports are only filed once a year, meaning if Pruitt's defense fund was created this year, he'd report it for the 2018 calendar year, which isn't required to be filed until May 2019 at the earliest. Of course, that means if Pruitt created the fund in the 2017 calendar year, it would be in the financial disclosure report that Pruitt recently got an extension to file. Read more.

BRIDENSTINE: 'GREENHOUSE GAS IS WARMING THE PLANET': NASA's Jim Bridenstine held his first town hall as administrator Thursday, where he clarified his stance on climate change. He said his position

on the issue has "evolved," and he described the impact of tornadoes in his home state. "I don't deny the consensus that the climate is changing, in fact I fully believe and know that the climate is changing," Bridenstine said. "I also know that we human beings are contributing to it in a major way." The former Oklahoma lawmaker, who was recently confirmed to the agency, faced previous criticism from Democrats over his denial that climate change is caused by humans. During Thursday's address, Bridenstine instead praised the work of NASA and defined carbon dioxide as a greenhouse gas. "We're putting it to the atmosphere in volumes that we haven't seen and that greenhouse gas is warming the planet," he said. "That is absolutely happening and we are responsible for it." Watch his remarks here.

MORE CALLS FOR RELEASE OF CHEMICAL SAFETY STUDY: Calls continue to mount for the Trump administration to release a hot-button assessment of the chemicals PFOA and PFOS that POLITICO reported Monday was described as a "public relations nightmare" by a White House official. New York Democratic Rep. Sean Patrick Maloney will add his voice to the chorus with a letter to Pruitt today. Maloney's Hudson River Valley district includes Newburgh, N.Y., where the chemicals have leached from the nearby Stewart Air National Guard Base. State-funded blood tests have found that residents there have more than three times the amount of PFOS in their blood than the average American.

HOUSE APPROPRIATIONS SCIENCE BILL ADVANCES: The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill Thursday on a party-line vote of 32-19. The fiscal 2019 measure would increase spending for federal law enforcement, NASA and the National Science Foundation by $2.9 billion to a total of $62.5 billion, Pro's Hugh Ferguson and Sarah Ferris report. NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request. Among the 18 amendments offered, two Democrat-offered NOAA-related ones were withdrawn. One was related to increasing funding for coastal resilience programs at NOAA, and another would increase funding for the NOAA climate research program.

Speaking of NOAA: The agency found April 2018 marked the 400th consecutive month with temperatures above average. Additionally, NOAA said the average global temperature for April was 1.49 degrees F above the 20th-century average of 56.7 degrees — the third highest for April in the 139-year record, with 9 out of the 10 warmest Aprils occurring since 2005.

CLIMATE CAUCUS WELCOMES FIVE MEMBERS: The Climate Solutions Caucus welcomed five new members to its ranks on Thursday: Reps. Erik Philip Paulsen, Tom MacArthur, Eliot Engel, Peter Roskam and Ron Kind. The additions bring the bipartisan caucus' total to 78 members.

CORPS GRID RESTORATION ENDS TODAY: At the direction of the CEO of the Puerto Rican power company PREPA and the Energy Unified Command Group, FEMA said that as of today the Army Corps of Engineers will no longer provide line restoration work for the power authority. Instead, PREPA will oversee its contractors and the remaining work in grid restoration. PREPA reports 98.86 percent of pre-storm customers have had their power restored, with 16,723 remaining without power, as of Wednesday.

But FEMA said Thursday it had approved the extension of an Army Corps mission assignment that allows for the lease, generation and maintenance of three "mega generators" until PREPA completes its purchase of the generators.

NATURAL GAS AND NATO: Although it was not immediately clear how, Trump said Thursday gas would play a role in upcoming NATO talks. The president remarked on Germany's relationship with Russia during his meeting with Secretary-General Jens Stoltenberg, who praised Trump for pushing countries in the alliance to boost their defense spending. In his remarks, Trump specifically called out Germany for its "longstanding shortfall in defense contributions." Trump called the member nation "a very big beneficiary" that "must demonstrate leadership." He added, "they're buying massive amounts of gas from Russia and paying billions

and billions of dollars. So I think that's something we'll be discussing later and we'll be discussing that at our meeting, and probably long before the meeting." The leaders' meeting came ahead of a NATO summit in July.

Meanwhile, The Wall Street Journal reported on Thursday that U.S. and European officials said Trump told German Chancellor Angela Merkel in April that Germany should drop support for Nord Stream 2, an offshore pipeline that would bring gas directly from Russia via the Baltic Sea. This would be in exchange for the U.S. starting talks with the European Union on a new trade deal.

DEPARTMENT OF CORRECTIONS: The New York Times set the record straight last night, issuing a correction to its story from April 13 that said the former head of Pruitt's security detail, Pasquale "Nino" Perrotta, had met for drinks with an an official from the EPA inspector general's office. That report had raised concerns in some quarters about the independence of the IG investigator.

The story, the paper said, "erroneously included Mr. Perrotta among those who gathered for beers at an event at the Elephant and Castle in Washington that was attended by Patrick Sullivan, the assistant inspector general who oversees investigations at the E.P.A. Mr. Sullivan said that Mr. Perrotta had been invited but did not attend that gathering and that he has never met for drinks with Mr. Perrotta, though he acknowledged that the two men met for lunch several months later at another restaurant near the E.P.A. headquarters."

MAIL CALL! Democratic Sens. Ed Markey, Sheldon Whitehouse and Tom Carper , members of the EPW Committee, called on EPA to publicly release a health assessment on the effects of formaldehyde exposure. They cite an exchange between Markey and Pruitt during his January appearance before the committee where Pruitt said he'd get back to the senator on the progress of the report. "Unfortunately, it appears that the agency may be succumbing to pressure from industry in its attempt to delay or block the publication of the formaldehyde health assessment," they write. Read it here.

CONGRATS ARE IN ORDER: Barrasso congratulated Wyoming Gov. Matt Mead in a letter this week on the dedication of the state's Integrated Test Center near Gillette. The carbon capture research facility, dedicated Wednesday, is a testing space off the back of the operating coal power plant. Five Carbon XPrize finalists — U.S., Canada, India, China and Scotland — will head to the site to put their concepts to capture CO2 from the power plant and convert it to a marketable product to the test. In his letter, Barrasso called the ITC "an important resource for Wyoming's economy." Read it here.

ROCKET TO THE SUN: House Science Chairman Lamar Smith said Thursday he submitted the names of committee members and staff to be placed aboard the Parker Solar Probe on its "mission to touch the Sun." NASA opened up the opportunity to the public to submit names to be stored on a memory card and installed on the probe before it launches this summer. "When I came across NASA's unique offer, I thought this would be a perfect and light-hearted opportunity to carve the names of the members and staff in history," Smith said in a statement.

SEE IT: Electricity generation will vary widely over the coming decades, according to U.S. Energy Information Administration's projections. Pro's DataPoint team breaks down the numbers in a graphic here. Want to add DataPoint to your Pro account? Learn more.

QUICK HITS

— Florida congressional delegation gives thumbs-down to offshore drilling, McClatchy.

— Republican lawmaker: Rocks tumbling into ocean causing sea level rise, E&E News.

— Emails show Interior expected to learn nothing from public input on Bears Ears review, Huffington Post.

— Zinke moves to protect critical minerals from foreign threats, Washington Examiner.

— Zinke tells greens he'll make 'grand pivot' to conservation, E&E News.

— Will Trump's pick to run EPA in California show up for work? Los Angeles Times.

HAPPENING TODAY

9:00 a.m. — House Energy and Commerce Environment Subcommittee hearing on various bills, 2123 Rayburn

9:30 a.m. — House Judiciary Regulatory Reform, Commercial and Antitrust Law Subcommittee hearing on "No Oil Producing and Exporting Cartels Act," 2141 Rayburn

12:00 p.m. — The National Capital Area Chapter of the United States Association for Energy Economics presentation on "How less-than-efficient humans interact with energy markets," 618 H St NW

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https://subscriber.politicopro.com/newsletters/morning-energy/2018/05/another-house-wotus-vote-maybe-222339

Stories from POLITICO Pro

GOP leaders, Freedom Caucus face off on farm bill, immigration Back

By Liz Crampton, Helena Bottemiller Evich and Rachael Bade | 05/17/2018 04:34 PM EDT

House GOP leaders are daring the Freedom Caucus to sink their prized partisan farm bill, pushing ahead with a Friday morning vote despite conservative threats to tank it.

Speaker Paul Ryan's team haggled late into the night Thursday with Freedom Caucus leaders. To win the far-right, leaders gave the group what it originally asked for: the promise of a vote on a conservative immigration bill — albeit not until June.

But the Freedom Caucus retorted that they want the immigration roll call now before the farm bill gets a vote. Some fear leadership will renege on that vow, as they have on the issue in the past.

After Ryan's team explained to the group late Thursday that they could not do immigration before the farm bill, the group of conservatives held a conference call to discuss what to do.

With the vote still scheduled for Friday morning, it is unclear where things stand. GOP leaders are waiting for word on whether the Freedom Caucus will deliver the final votes needed to push the bill over the finish line. President Donald Trump, meanwhile, tweeted about the matter, asserting pressure on the right to get in line.

"Tomorrow, the House will vote on a strong Farm Bill, which includes work requirements," Trump wrote, referring to a new mandate in the bill requiring those receiving food stamps to find employment. "We must support our Nation's great farmers!"

Tensions over the farm bill escalated Thursday afternoon when Freedom Caucus Chairman Mark Meadows announced that his three-dozen members would not support the measure. In return for their vote, the North Carolinian said they'd need a vote on a bill crafted by Judiciary Chairman Bob Goodlatte that extends Dreamers' legal status for a host of conservative immigration policies.

"At this point there is no deal to be made," Meadows said exiting an hour-long Freedom Caucus powwow. "The vast majority of our members believe we should have a vote on immigration before the farm bill."

He added: "At this point there's not enough votes to pass the farm bill."

Even after the group rejected that offer, House Majority Leader Kevin McCarthy maintained that he was not pulling the bill from the floor. Senior Republicans are holding out hope that they could reach some sort of accord by Friday.

The scheme by conservatives could throw at least a temporary wrench in Ryan's welfare overhaul push. The farm bill, which covers agriculture subsidies, conservation, rural development and nutrition, would impose stricter work requirements on between 5 million and 7 million food-stamp recipients. The current farm bill expires Sept. 30.

With Democrats planning to vote against the farm bill because of the new work requirements, Republicans need the votes of the Freedom Caucus for the measure to pass.

The scramble to try to bring the bill to a vote this week highlights the deep divisions within the Republican Conference. On the right, conservatives have been lukewarm at best on the sweeping bill, arguing it both doesn't go far enough on work requirements for able-bodied adults receiving food stamps, and does nothing to rein in farm subsidies. Several Republican moderates, meanwhile, have quietly raised concerns about the work requirements.

Ryan has long been eyeing the bill as a rare chance to enact a piece of a welfare overhaul, a key priority for the outgoing speaker. It's the first farm bill cycle in decades where Republicans control both chambers of Congress and the White House.

Even if the leaders strike a deal with conservatives, the version of the bill is considered a nonstarter in the Senate. Senate Agriculture Chairman Pat Roberts (R-Kan.) and ranking member Debbie Stabenow (D-Mich.) are drafting a bipartisan bill. Roberts has said the Senate will not include work requirements, citing his need to get 60 votes.

The food stamp program, now formally known as the Supplemental Nutrition Assistance Program, helps more than 40 million low-income Americans buy groceries each month.

The program has long had bipartisan support as well as backing from large food companies and retailers, who now see SNAP as big business. But SNAP's rolls expanded greatly in the wake of the Great Recession, and while the numbers have come down somewhat, they have not returned to pre-recession levels.

While the farm bill has historically been passed by a coalition of urban and rural lawmakers from both sides of the aisle, talks between Republicans and Democrats broke down earlier this year in the House Agriculture Committee over the work requirements, making the process unusually bitter and partisan.

"The farm bill also keeps faith with these families by not only maintaining SNAP benefits but by offering SNAP beneficiaries a springboard out of poverty to a good paying job, and opportunity for a better way of life for themselves and their families," House Agriculture Chairman Mike Conaway (R-Texas) said when he unveiled the bill last month.

The bill would require adult SNAP recipients between the ages of 18 and 59 to work or be enrolled in a training program at least 20 hours per week. People who are disabled, pregnant or caring for a child under the age of 6 would be exempt. The plan would also expand the pool of money for state-run work training programs tenfold, from $90 million per year to $1 billion.

The plan to go along with a GOP-only farm bill was originally Ryan's, according to senior Republican sources. The bill is seen as a personal priority for the speaker, who will retire at the end of the year and has long eyed enacting comprehensive welfare reform.

With leadership relying only on Republican votes for the bill, the House Freedom Caucus saw their opportunity for leverage.

Meadows acknowledged that the farm bill is the last must-pass legislation before the federal government spending bill must be approved in October. "Obviously when you look at that it's a leverage point," he said.

Catherine Boudreau contributed to this report.

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Shuster: House WRDA bill coming Friday Back

By Annie Snider and Anthony Adragna | 05/17/2018 03:14 PM EDT

The House Transportation and Infrastructure Committee will release its Water Resources Development Act Friday, Committee Chairman Bill Shuster said.

The measure has the support of the committee's ranking member, Rep. Peter DeFazio (D-Oreg.), as well as the top Democrat and Republican on the Water Resources and Environment Subcommittee, according to Rep. Garret Graves (R-La.), chairman of that subcommittee.

The House bill is expected to differ significantly from the upper chamber's measure. Graves said it will include language relating to one of his top priorities, moving the Army Corps of Engineers out of the Defense Department. Both Democrats and Republicans on the Senate Environment and Public Works Committee have been wary of that idea. However, Graves indicated the House bill will not call for an immediate move.

"There's a number of steps to the process in terms of how I think this will ultimately be done," Graves told POLITICO. "We do need to take a careful, constructive path forward because you don't want to come in and do something that's actually going to make it worse."

The Senate EPW Committee plans to mark up its bill next Tuesday, Committee Chairman John Barrasso (R-Wyo.) said today. He said he has not spoken with his House counterparts about their bill in the last couple of days and said the chambers are not coordinating their efforts.

WHAT'S NEXT: The House Transportation and Infrastructure Committee is expected to unveil its WRDA bill Friday. A markup could come as soon as next week.

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Obama touts climate executive order: Back

By Andrew Restuccia | 03/19/2015 12:02 PM EDT

President Barack Obama said this morning that his administration is "leading by example" by requiring the government to slash its greenhouse gas emissions.

"This has been a team effort to make sure that we're doing everything we can to boost the energy efficiency of the federal government," Obama said during brief remarks at the Energy Department.

And he made the case that policymakers can deal with climate change, while also protecting the economy.

"We're proving that it's possible to grow our economy robustly, while at the same time doing the right thing for our environment and tackling climate change in a serious way," he said.

Obama signed an executive order this morning that sets a goal of cutting the federal government's greenhouse gas emissions by 40 percent from 2008 levels over the next 10 years.

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House clears nuclear waste bill that would move Yucca forward Back

By Anthony Adragna | 05/10/2018 11:27 AM EDT

The House today cleared nuclear waste legislation, H.R. 3053 (115), that would kick-start the stalled Yucca Mountain repository while also establishing an interim storage facility for spent nuclear waste.

Overcoming the strong objections of Nevada lawmakers, the bill passed 340-72, with bipartisan support. It would offer incentives to the state for allowing Yucca to advance, include federal land transfers associated with the site and change how user fees are collected to help build the repository, among other provisions.

"I think people are ready to do something rather than nothing," Rep. John Shimkus (R-Ill.), the bill's sponsor, told reporters earlier this week.

Key to getting the bill to the floor was breaking a monthslong "impasse" with House Appropriators on how to spend revenues collected through the Nuclear Waste Fund, an account containing tens of billions built on fees on nuclear-generated electricity. Shimkus said his compromise will allow lawmakers "be more honest brokers" going forward by walling off future collected fees from being spent on other programs.

Lawmakers rejected an amendment from long-time Yucca opponent Rep. Dina Titus (D-Nev.) concerning consent-based siting, while adopting other amendments requiring clearer annual reports on the Nuclear Waste Fund balance and a report on resources for communities dealing with nuclear waste issues.

WHAT'S NEXT: Shimkus said he doesn't expect to see the bill taken up in the Senate, where Yucca opponent Sen. Dean Heller (R-Nev.) faces a competitive reelection.

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Some GOP appropriators resist Trump cutbacks Back

By Sarah Ferris and Kaitlyn Burton | 05/11/2018 05:03 AM EDT

Several GOP spending chiefs have cast doubt on President Donald Trump's proposed list of $15.4 billion in cutbacks, saying they're not yet ready to bury some of the targeted programs.

White House officials have pitched their rescissions package, H.R. 3 (115), as entirely noncontroversial, with some of the money sitting unused in accounts for two decades. Neutral experts have confirmed that the vast majority of the cutbacks would have zero programmatic effect.

But some longtime appropriators, including Senate Appropriations Chairman Richard Shelby (R-Ala.), are withholding support, even as most of their GOP colleagues flock behind Trump's first major attempt at deficit reduction to get a vote in Congress.

Some say they're skeptical of the administration's efforts to fast-track cuts to programs they aren't ready to kill, like rural infrastructure, clean energy and even a relatively new initiative that lets states use cash from unfinished earmarks projects.

"There's a lot of things there that don't make a lot of difference, but appropriators don't like rescissions, so we're going to have to think about that," Rep. John Carter (R-Texas), who oversees the Homeland Security bill, told POLITICO on Wednesday.

That initial resistance includes Sen. Lisa Murkowski — whose vote could help determine whether the bill passes the narrowly divided Senate. With Arizona Sen. John McCain's absence, Republicans have a 50 to 49 majority, and can't afford to lose a single GOP vote.

Murkowski (R-Alaska) said she isn't sold on the administration's proposal to cut $684 million from a clean energy loan guarantee program. "I want to make sure that if you take the funds from the account, you don't eliminate the program," the Interior-Environment Subcommittee chairwoman told reporters Thursday. "I don't want Title 17 programs eliminated. I want them reformed."

Rep. Mike Simpson (R-Idaho), who holds that position in the House, said Thursday he is "leaning no" on the proposal for the same reason. He said the clean energy program is "something I want to continue."

Shelby said he's concerned about cuts to the Appalachian Development Highway System. The White House has proposed $45.2 billion in cuts to that program, which the House matched in its bill unveiled Wednesday night.

"My state has benefited from that over the years," Shelby told reporters, noting that the bill could still see tweaks before it comes to a vote in the Senate. "I'm waiting to see what comes up first and where it comes up."

As a 24-year veteran of the Appropriations panel, Shelby is one of few sitting lawmakers to witness the last round of rescissions in 2000. And he said any cost-cutting proposal from 1600 Pennsylvania Avenue is likely to find at least a few critics on Capitol Hill.

"Since I've been up here — and I've been up here a few years — there's always some things in the rescissions package that a lot of members are committed to," Shelby said.

Meanwhile, Rep. Mario Diaz-Balart (R-Fla.) complained that the rescissions bill would roll back money that states could use for items such as infrastructure projects. That's because states can now access old cash that was earmarked for efforts that didn't get off the ground.

"Now, if you take it out, you're taking money out of the states' funds," the Transportation-HUD panel chairman said. "If you believe, like me, that infrastructure is a needed investment, I think that's problematic taking that away."

Appropriators are a fiercely independent breed on Capitol Hill, faced with a declining share of influence in the recent stop-and-go funding cycle. Now, they've been handed the largest-ever presidential rescissions request without a chance to vet it through their committees.

House GOP leaders are planning to bring the bill directly to the floor for a vote, as soon as next week. The Senate is expected to follow suit.

The Office of Management and Budget has said the $15.4 billion rescissions proposal would actually amount to less than $3 billion in spending cuts.

What's alarming to appropriators, though, is that the proposal would drain from Congress' ever-dwindling pool of "offsets," the equivalent of a rainy day fund for pending legislation.

The money that would be trimmed from the Children's Health Insurance Program, a federal fund for low-income families, for instance, has been used to help pay for the annual Labor-HHS-Education bill for years.

"Look, there's $5 billion of CHIP money that you can't spend. Why wouldn't you reclaim that money and put it back in the federal treasury?" asked Rep. Tom Cole, (R-Okla.), who oversees Labor-HHS-Education spending. "Or you can use it for an offset on something, which is normally what we've done in the past."

Cole is one of four appropriators to co-sponsor the package, along with Republican Reps. Tom Graves of Georgia, Kay Granger of Texas and Steve Womack of Arkansas. Of those, everyone but Womack is running for House Appropriations chairman this fall. And Womack is the leader of the House Budget Committee.

(The other contender for the House spending panel's gavel, Rep. Robert Aderholt (R-Ala.), was the first appropriator to go on record supporting the idea last month.)

"It's been carefully drawn, it doesn't violate our omnibus agreement, it doesn't violate our defense bill," Granger told POLITICO this week. Granger's panel oversees the Pentagon's budget, which wouldn't see a dollar cut under the White House's package.

Cole acknowledged that the dwindling pool of offsets would "probably" make it tougher for Congress to pay for some legislation down the road. But he said there are plenty of other ways to pay for something if leadership looked hard enough.

"In a $4 trillion budget, there's always something you can find to offset something else if it's really politically important enough to do," Cole said.

Anthony Adragna contributed to this report

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Democrats fear Pruitt's legal defense fund could create conflicts of interest Back

By Alex Guillén | 05/16/2018 04:38 PM EDT

EPA Administrator Scott Pruitt's newly formed legal defense fund has the embattled administrator's critics wondering whether companies he regulates will come to Pruitt's rescue behind the scenes.

Legal defense funds are subject to few formal rules, although any donations to help pay for Pruitt's lawyers would have to abide by existing ethics rules, including limitations on gifts from lobbyists or those with business before an official. While the Office of Government Ethics in September issued nonbinding guidance recommending that executive branch officials reject anonymous donations and consult with ethics officials before establishing such funds, critics say the system is ripe for potential abuse.

"You can see the conflicts," Sen. Tom Udall (D-N.M.) told reporters Wednesday, after pressing Pruitt on the legal defense fund during a congressional hearing. "A business is saying, 'I want this regulation to be repealed and so I'm going to give $100,000 to your legal defense fund.' That kind of activity just shouldn't be happening."

Experts say that even with those ethics boundaries, Pruitt will have significant leeway in deciding just how transparent the fund will be.

Craig Holman, a government affairs lobbyist at Public Citizen, compared the situation to the "Wild West."

"Legal defense funds in the executive branch can be set up any way the official prefers, including refusing to disclose the sources and amounts of donations," said Holman, who has petitioned OGE to create official rules for such funds.

In Pruitt's case, the fund must be set up as a private entity run by an independent third party and should not ask for donations from energy companies or lobbyists in order to comply with ethics laws, said Don Fox, a former general counsel and acting director for OGE. As for any other restrictions, he said, "OGE says, basically, 'We don't bless this; we're not telling you whether this good, bad or indifferent, but if you follow these guidelines, you should be OK.'"

Pruitt, who was an accomplished political fundraiser before joining the Trump administration, said the fund had been set up by his attorneys, not himself.

Pruitt told lawmakers on Wednesday that his attorney "who's done this for a number of years" has worked with the GAO "to make sure it's done properly."

He also said he would follow the advice of the White House Office of Legal Counsel on whether to accept anonymous donations, but he did promise not to personally solicit money from lobbyists or companies with business before EPA.

Asked by Sen. Chris Van Hollen (D-Md.) whether he would commit "not to accept donations from lobbyists or corporations that have business before the EPA," Pruitt replied, "Absolutely," although he then amended that statement.

"Let me clarify something. I don't accept the donations; I don't solicit donations. That's done by attorneys and others," Pruitt told the Maryland Democrat at Wednesday's hearing before a Senate Appropriations subcommittee. Pruitt said he would follow the advice of GAO and the White House regarding whether to accept anonymous donations.

As a rising star attorney general in Oklahoma several years ago, Pruitt raised millions for his own campaigns and outside conservative groups. Pruitt helped land millions of dollars in donations from the energy industry to the Republican Attorneys General Association, where he served several years as chair and an executive board member.

Major donors to RAGA during that time included Koch Industries and Devon Energy, an Oklahoma-based oil and gas company with close ties to Pruitt.

Pruitt later chaired the Rule of Law Defense Fund, but that group is not required to disclose its donors.

He also created a leadership PAC and a super PAC to promote his interests. Each one had raised about $45,000 but gave that money away and shut down once he was nominated to run EPA.

Pruitt did not specify which attorney set up his fund. The Washington Post on Wednesday reported it is run by Cleta Mitchell, an attorney at Foley & Lardner.

Mitchell did not answer questions from POLITICO about the fund.

"I do not respond to questions from reporters about any legal matters in which I may or may not be involved," Mitchell wrote in an email. "Administrator Pruitt has been a friend and client for a number of years."

Mitchell was a Democrat in Oklahoma's House of Representatives from 1976 to 1984, but her later law practice focused on representing conservatives, including Sen. Jim Inhofe (R-Okla.). She is a former board member of the National Rifle Association and the American Conservative Union, which runs the annual conservative confab known as "CPAC."

Mitchell has come to Pruitt's defense on Twitter in recent months.

On April 6, shortly after The New York Times reported that Pruitt had removed or reassigned career and political officials who questioned his actions, Mitchell tweeted: "NYT is outraged that Scott Pruitt moved EPA employees who fought his initiatives. That's exactly what we WANT him to do."

She tweeted a few days later that Sen. Sheldon Whitehouse (D-R.I.) "and his crazy environmentalist cronies have FED the hostility against Pruitt. Pray for Pruitt's safety."

Ben Lefebvre, Annie Snider and Anthony Adragna contributed to this report.

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How Trump's climate skeptics are changing the country Back

By Emily Holden | 03/07/2018 05:02 AM EDT

President Donald Trump is filling the upper ranks of his administration with appointees who share his disbelief in the scientific evidence for climate change — giving them an opportunity to impose their views on policies ranging from disaster planning to national security to housing standards.

At the Interior Department, decisions about Pacific island territories threatened by rising seas are in the hands of an assistant secretary who has criticized "climate alarmists" for "once again predicting the end of the world as we know it." Agriculture Secretary Sonny Perdue's top advisers include a former talk radio host who has dismissed much climate research as "junk science." Trump's nominee to head research and technology at the Department of Transportation claimed three years ago that global warming had "stopped" — a position at sharp odds with the findings of federal agencies like NASA.

Trump has chosen at least 20 like-minded people to serve as agency leaders and advisers, according to a POLITICO review of his appointees' past statements on climate science. And they are already having an impact in abandoning former President Barack Obama's attempt to help unite the world against the threat of rising sea levels, worsening storms and spreading droughts.

[Sneak preview for Pro subscribers: Trump's climate science doubters]

Most famously, the president and his team have scrubbed mentions of climate change from government websites, kicked scientists off advisory boards, repudiated the Obama administration's greenhouse gas regulations and made the U.S. the only nation on Earth to reject the 2015 Paris agreement on global warming.

More quietly, Trump's White House excluded rising temperatures from the list of threats in its December national security strategy, contradicting the approach of both the Obama and George W. Bush administrations. Last year, just before Hurricane Harvey drowned Houston, the White House rescinded requirements that projects built with federal dollars take into account the way warming temperatures might intensify extreme weather.

People worried about the consequences of climate change say a government that denies the problem is courting danger.

"The analogy could be if somebody's got a heart problem or high cholesterol, you take medicine that helps manage that so you can avoid a heart attack," said Ana Unruh Cohen, the government affairs director at the Natural Resources Defense Council. "Trump taking that away, saying, 'Forget it, I don't believe I have high cholesterol,' is setting up the country for a heart attack."

Aparna Mathur, a resident scholar in economic policy at the conservative American Enterprise Institute, found the trend worrying as well.

Many administration officials "don't seem to believe climate change is real, or if they believe climate change is real, there's this sort of attitude that there's not much to do about it or it's not caused by human actions," said Mathur, whose AEI colleagues also include people who question the extent of man-made climate change. As a result, she said, the U.S. is falling behind countries that are taking action on the problem.

The doubts are coming from both prominent and little-known Trump appointees, in ways both obscure and subtle.

Some have expressed doubt that the Earth is warming at all, speculated that the trend might be good for humans, or said it's just impossible to know how much of a role humans and their pollution are playing. All these statements fly in the face of findings by the government's own research agencies and the vast majority of climate scientists.

"There are scientists that think lots of different things about climate change," then-Rep. Mike Pompeo (R-Kan.), now Trump's CIA director, said on C-SPAN in 2013. "There's some who think we're warming, there's some who think we're cooling, there's some who think that the last 16 years have shown a pretty stable climate environment." Pompeo dodged the issue in his confirmation hearing last year, saying he would "prefer today not to get into the details of the climate debate and science."

When he was running for president, HUD Secretary Ben Carson scoffed at the idea that strong evidence for human-caused climate change even exists. "I know there are a lot of people who say 'overwhelming science,' but then when you ask them to show the overwhelming science they never can show it," he told the San Francisco Chronicle in 2015.

Few have been as publicly outspoken on the issue as Trump, who more than once has dismissed human-caused climate change as a "hoax" and claimed in January that polar ice isn't melting.

The White House sought to strike a somewhat more moderate tone in a statement to POLITICO on Monday, which said that "the climate has changed and is always changing. The Administration supports rigorous scientific analysis and debate." The statement from principal deputy press secretary Raj Shah added that "the development of modern and efficient infrastructure ... will reduce emissions and enable us to address future risks, including climate related risks."

Some of the administration's climate skeptics have already come and gone.

Former HHS Secretary Tom Price, who had criticized the "allegedly 'settled science' of global warming" as a member of Congress, resigned in September amid criticism of his expensive travels on government and private planes. Kathleen Hartnett White, Trump's pick to head the White House Council on Environmental Quality, withdrew her nomination earlier this year after she stirred criticism with a long list of controversial statements , including calling the human role in climate change "very uncertain."

Another unsuccessful nominee, former talk radio host and political science professor Sam Clovis, had to pull out of the running to be USDA's chief scientist after critics noted that he has no science credentials — but he remains a top adviser to Perdue. Clovis dismissed much climate research as "junk science" in a 2014 interview, adding that "a lot of this global warming ... is really about income redistribution from rich nations that are industrialized to nations that are not."

Brent Fewell, a conservative environmental lawyer who was an EPA water official under Bush, suggested that some of these officials may privately acknowledge that man-made climate change is real. But he added: "A lot

of people on the political right are uninformed about the issue. For whatever reason, it's a lot easier to simply agree with the prominent voices in the political party."

The upshot is the same, however: a 180-degree reversal from Obama's efforts to make the U.S. a leader in addressing the causes and consequences of a warming planet.

The EPA is leading the charge by withdrawing or weakening a host of climate regulations, including a 2015 rule that would have sped the electric power industry's shift away from coal-fired energy. Trump has also approved tariffs for solar panel imports, which will make it harder for green energy to compete with fossil fuels. Agencies have sought to cancel rules meant to limit the oil and gas industry's methane pollution — another major greenhouse gas source — and are reconsidering tougher standards for vehicles, too.

The Energy Department has proposed regulatory changes to prop up coal plants that can't compete in the market, while the White House is seeking buyers for U.S. coal and gas exports.

When Trump's critics seek to challenge these actions in court, the government's defense will be run by the Justice Department — an agency whose leader, Attorney General Jeff Sessions, said during a 2015 Senate hearing that carbon dioxide is "really not a pollutant."

"It's a plant food, and it doesn't harm anybody except that it might include temperature increases," Sessions said.

Some agencies are still continuing to study climate change and factor their findings into their policy decisions. But even there, career staffers may not talk about their work as openly as they once did, and the agencies seldom showcase it the way they did during the Obama years.

Much of the alarm among Trump's critics focuses on EPA, which has replaced dozens of scientists on its key advisory boards with industry or state representatives, and has found other ways to keep researchers from contradicting the administration's message. Last fall, the agency canceled an appearance by three EPA scientists scheduled to speak about climate change at a Narragansett Bay conference . Both EPA and the Energy Department have given extra scrutiny to grant proposals with the words "climate change," and in the case of EPA, it has put a political appointee in charge of signing off on them, The Washington Post has reported.

All this is in line with the public statements of EPA Administrator Scott Pruitt, who has suggested that global warming might be a good thing and has spoken about holding a public debate on whether climate change is real.

"Right out of the gate ... the administration took any and all mention of climate change off of the White House website," said Jacob Carter, a research scientist who has been tracking the administration's treatment of science for the Union of Concerned Scientists. "It seems like the administration is really trying to undo a lot of the scientific process as a whole and get experts out of the way."

The Environmental Data and Governance Initiative, which has studied the purging and rewording of climate-related documents on government websites, reported at the end of 2017 that it had found a "significant loss of public access to information about climate change."

The State Department's website took down links related to the Paris climate agreement, EPA removed a student's guide to climate change, and the Energy Department got rid of the words "clean energy" on a page with information for investors and businesses looking for projects with national laboratories.

The Interior Department's Bureau of Land Management, which oversees energy development on federal land, cut text about the effects of climate change. Some of the resources are still technically available in archives or in new locations, but they are harder to find because the government sites don't directly link to them, the Environmental Data and Governance Initiative says.

"It's not alarming the public because it's very hard to see each incremental thing," said Andrew Bergman, a co-author of the report.

Some Trump appointees have downplayed the idea that agency leaders' personal views about climate change are critical to making policy, suggesting they can still respond to global warming's effects without addressing why it's happening.

"We continue to take seriously climate change — not the cause of it, but the things that we observe," Tom Bossert, the president's homeland security adviser, told reporters after last year's spree of catastrophic hurricanes that ravaged Houston, Puerto Rico and the Virgin Islands.

Sarah Hunt, who works in energy policy at the conservative American Legislative Exchange Council, said that "policymaker views on climate science needn't have any bearing on their support for conservative clean energy policies that spur the innovation we need to reduce emissions and promote environmental stewardship while we grow our economy."

But Trump's actions have reflected his views on the science. For example, one of his early executive orders in March 2017 eliminated a number of ways agencies had been required to consider climate change, including in environmental reviews for infrastructure projects.

Because so many of his appointees have questioned the conclusions of climate scientists, they are jettisoning climate change from routine processes. Those include EPA's refusal to consider the global monetary benefits of curbing rising temperatures when it rolled back Obama-era rules for the power sector.

Still, some agencies have continued to issue major reports that warn that climate change is a real and growing problem — even as the president's staffers push the message that the science is uncertain.

In November, the government's 13-agency National Climate Assessment concluded that humans have pushed global temperatures to their highest level in modern times. In January, NASA published data showing that last year was the second-warmest on record, and noted that temperature rises are "driven largely by increased carbon dioxide and other human-made emissions into the atmosphere."

Trump's nominee to run the space agency, Rep. Jim Bridenstine (R-Okla.), criticized "climate change alarmists" on the House floor in 2013 and claimed that "global temperatures stopped rising 10 years ago." (In fact, they haven't.) At his confirmation hearing last year, he acknowledged that humans are a cause of climate change but wouldn't call them the main cause.

"That is a question that I do not have an answer to," he said.

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House panel green-lights Commerce-Justice-Science bill Back

By Hugh T. Ferguson and Sarah Ferris | 05/17/2018 04:19 PM EDT

The House Appropriations Committee advanced its fiscal 2019 Commerce-Justice-Science bill, marking its fifth completed bill of the spending cycle. The vote was 32-19, along party lines.

In a rare bipartisan moment in the five-hour markup, lawmakers agreed to add a provision to uphold sanctions against the Chinese phone-maker ZTE, just days after President Trump declared he is seeking to lessen the penalties.

Another bipartisan addition would protect medical marijuana in states where it's already legal — language that was skipped over in last year's markup but adopted this year with barely an objection.

The fiscal 2019 measure would provide $62.5 billion for the wide-ranging Commerce-Justice-Science bill, which funds federal law enforcement, NASA and the National Science Foundation, a $2.9 billion bump above current levels.

The bill would fund the Department of Justice at $30.7 billion, an increase of $793 million from fiscal 2018. Within that, the FBI's budget would dip slightly, although it is still $400 million more than the White House request.

The budget for the U.S. Census would swell to $4.8 billion, nearly double the current levels, as officials ramp up for the 2020 survey.

NASA would get an $810 million boost, for a total of $21.5 billion — $1.6 billion above the Trump administration's request.

Another $447 million would go toward the national fight against opioid addiction, the same amount in this year's omnibus, H.R. 1625 (115).

House Democrats, along with a pair of Republicans, offered 18 amendments. Many were targeting specific riders that they viewed as partisan threats to the measure's passage.

The panel also unanimously backed a manager's amendment from subcommittee Chairman John Culberson (R-Texas). The amendment contained a number of provisions that each side had agreed upon, according to Culberson and Rep. José Serrano (D-N.Y.) ranking member of the subcommittee.

Amendments included:

— Barbara Lee (D-Calif.) amendment that would strip the measure of three firearm related provisions with the intent to reduce gun violence, rejected 20-31.

— Matt Cartwright (D-Pa.) amendment that would increase funding for the NOAA climate research program, withdrawn.

— Nita Lowey (D-N.Y.) amendment that would prevent individuals from purchasing a firearm by giving the attorney general the authority to deny the sale of a firearm to an individual buyer believed to be aiding in acts of terrorism, rejected 20-31.

— Lucille Roybal-Allard (D-Calif.) amendment that would prohibit the use of funds to prosecute immigrants who have illegally entered the U.S. seeking asylum unless they have committed serious criminal acts or present a danger to the U.S., rejected.

— David Price (D-N.C.) amendment related to eviction proceedings with competitive grant funding for legal services in high eviction areas, rejected 22-28.

— Dave Joyce (R-Ohio) amendment related to protections for state medical marijuana laws, adopted on voice vote.

— Dutch Ruppersberger (D-Md.) amendment related to moving the FBI into a new headquarters, withdrawn.

— Betty McCollum (D-Minn.) and Tom Cole (R-Okla.) amendment related to funding increase for tribal nations under the Crime Victims Fund, adopted on voice vote.

— Derek Kilmer (D-Wash.) amendment related to increasing funding for coastal resilience programs at NOAA, withdrawn.

— Debbie Wasserman Schultz (D-Fla.) amendment related to restoring stricter reporting rules for certain semi-automatic guns, rejected by voice vote.

— Henry Cuellar (D-Texas) amendment related to protecting land by limiting the government's eminent domain powers when it comes to building a border wall, rejected by voice vote.

— Ruppersberger amendment related to enforcing sanctions against ZTE, adopted by voice vote.

— Lowey amendment protecting the special counsel at the Department of Justice, rejected 23 to 27.

— Grace Meng (D-N.Y.) amendment related to increasing funding for juvenile delinquency prevention programs, withdrawn.

— Serrano amendment related to the new citizenship question on the 2020 U.S. Census, rejected by voice vote.

— Ruppersberger amendment related to federal grants tackling contraband cellphone use in prisons.

— Andy Harris (R-Md.) amendment related to DEA research on medical risks and benefits of marijuana, withdrawn.

— Ruppersberger amendment related to NASA satellite program, withdrawn.

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NATO chief thanks Trump for leadership on military spending Back

By Eli Okun | 05/17/2018 03:26 PM EDT

NATO Secretary-General Jens Stoltenberg praised President Donald Trump on Thursday for pushing countries in the alliance to boost their defense spending, an issue that has driven a wedge between Trump and Europe before.

"Let me thank you for the leadership you show on the issue of defense spending because it is very important that we all contribute more to our shared security, and it is really having an impact because, as you said, allies are now spending more on defense," Stoltenberg said while taking reporters' questions after the leaders met at the White House. "All allies are increasing their defense budgets."

"Do you give me credit for that?" Trump pressed.

"You have helped to do that," Stoltenberg said.

It was a notable moment for a U.S.-NATO relationship that has sometimes seemed on shaky ground during the Trump administration.

A minority of NATO's members — including the U.S. — meet the alliance's nonbinding guideline for each country to spend at least 2 percent of its GDP on defense.

Other American presidents have pressed their NATO allies to increase military budgets. But the issue has become a particular flashpoint for Trump, who is often skeptical of international alliances or deals that he deems unfair to the U.S.

"Together we've increased and really raised a lot of money from countries that weren't paying, or weren't paying a fair share," Trump said on Thursday. "We have a little ways to go, but many billions of dollars of additional money has been raised."

Stoltenberg later told the president: "Your leadership on defense spending has really helped to make a difference."

Trump noted that he thought the alliance should increase the standard to 4 percent.

Last year, Trump reversed his previous dismissals of the alliance and said he no longer considered NATO "obsolete." But he's continued to raise concerns about spending — including to Chancellor Angela Merkel of Germany last month.

Trump again singled out Germany on Thursday, calling it "a very big beneficiary" that "must demonstrate leadership."

And though Trump said the alliance needed to improve its counterterrorism capabilities, he repeated that the U.S. was committed to NATO's Article 5.

Early in his administration, Trump scared European allies by deciding on the fly to scrap a public affirmation of Article 5, the longstanding lynchpin of the alliance that guarantees the countries' commitment to mutual defense. But by June 2017, he committed to the article.

Though the president's decision last week to abandon the Iran nuclear deal angered European allies, Secretary of State Mike Pompeo, who took office last month, has made a more positive impression on NATO so far.

The leaders' meeting came ahead of a NATO summit in July.

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EPA watchdog: Investigator says he did not socialize with Pruitt security chief Back

By Alex Guillén | 04/13/2018 05:46 PM EDT

A top investigator at EPA's Office of Inspector General is disputing a report that he is friends with the head of Administrator Scott Pruitt's protective detail, according to a spokeswoman for the internal watchdog.

The New York Times reported Thursday that Patrick Sullivan, the assistant IG in charge of investigations, has been seen drinking beers at a bar across the street from EPA's headquarters with Pasquale "Nino" Perrotta, who last year became the head of Pruitt's security detail after his predecessor was removed.

Citing that report, a left-leaning nonprofit group on Friday requested an investigation from a council of federal inspectors general. But Sullivan says the Times got it wrong.

Sullivan "confirmed that he has never had drinks with Mr. Perrotta anywhere or at any time. He has never been to the Elephant and Castle with Mr. Perrotta," IG spokeswoman Tia Elbaum said in an email Friday.

While they had both previously worked for the Secret Service, Sullivan and Perrotta did not know one another until Sullivan began working for the EPA IG in 2011, according to Elbaum. "They are professional colleagues and friendly, but do not socialize outside of work," she said. (Perrotta, who has become a key figure in some of the controversies surrounding Pruitt, arrived at EPA in 2004, and initially worked at the OIG but moved to the security detail before Sullivan was hired.)

Another spokesman for the OIG said they have not yet asked for a retraction but may do so in the future.

A spokesperson for the Times said the paper stands by its story.

The watchdog group Citizens for Responsibility and Ethics in Washington on Friday asked for an investigation into their relationship.

The alleged socialization is "conduct that may undermine the independence or integrity reasonably expected of Mr. Sullivan," wrote CREW in a letter to officials at the independent Council of the Inspectors General on Integrity and Efficiency.

The Times did not specify the source or sources who claimed to have spotted Sullivan and Perrotta having drinks, but its original report said a spokesman for EPA's inspector general had disputed that the two men socialized outside of work. The story does not appear to have been updated since it was first published.

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Message

From: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Sent: 10/22/2016 8:47:58 PM
To: Bussard, David [Bussard.David@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]
CC: Birchfield, Norman [Birchfield.Norman@epa.gov]; Cogliano, Vincent [cogliano.vincent@epa.gov]
Subject: Revised faldh rat nasal cancer d-r section attached
Attachments: Ravi Revised Main.docx

Please edit this directly (preferred) as necessary.

--Ravi.

Ravi Subramaniam
Chief, Toxic Effects Branch, IRIS, ORD, US EPA
(571) 305-3601

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 5/28/2015 5:35:23 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]; Barbara Glenn [glenn.barbara1@gmail.com]
Subject: MOA and genotox
Attachments: Appendix 1 lhp moa 051515.docx; Modes of action for Lymphoma revised draft 051515.docx; Genotox_Study_Eval_020615.docx; FormaldehydeAppendixdraft070113forREVIEW-revised_041515.docx; Formaldehyde and polymorphism.docx

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 10/10/2017 2:47:27 PM
To: Lidka Maslankiewicz [lidka.maslankiewicz@rivm.nl]; Kraft, Andrew [Kraft.Andrew@epa.gov]
CC: Bussard, David [Bussard.David@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]; Els Smit [els.smit@rivm.nl]; Joke Herremans [joke.herremans@rivm.nl]; Paul Janssen [paul.janssen@rivm.nl]; Thayer, Kris [thayer.kris@epa.gov]; Theo Vermeire [theo.vermeire@rivm.nl]
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Lidka,
We would like to schedule a time to talk about the formaldehyde assessment and its methods for quantification of cancer risk for NPC. It would be great to explore what might be possible. I have some proposed dates and times for you to select from. Will this be possible for you?

Oct. 30 9 – 10 am EST
Nov 1 9 – 10 am EST
Nov 7 9 – 10 am EST

Thank you very much for your patience with our process and timing. Regards, Barbara and Andrew

From: Lidka Maslankiewicz [mailto:lidka.maslankiewicz@rivm.nl]
Sent: Friday, September 22, 2017 4:54 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Els Smit <els.smit@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Joke Herremans <joke.herremans@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Thayer, Kris <thayer.kris@epa.gov>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Andrew and Barbara

Thank you for your reply, apologies for not answering sooner.

The issue is that we would like to use the data as presented in the 2010 Draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data.

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer? Something in line with: *"It should be noted that the methodology used for the quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."*

We also noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

Maybe we can first do the exchange via mail and decide later on if a telephone conference is useful.

Kind regards

Lidka

Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
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+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

From: "Kraft, Andrew" <Kraft.Andrew@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>,
Cc: Els Smit <els.smit@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Joke Herremans" <joke.herremans@rivm.nl>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Bussard, David" <Bussard.David@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>
Date: 09/08/2017 05:21 PM
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment . We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations,
Andrew and Barbara

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Tuesday, August 29, 2017 7:59 AM
To: Kraft, Andrew
Cc: Els Smit; Paul Janssen; Joke Herremans
Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,
My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.
We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response" (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the

Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ...
cfpub.epa.gov
EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ...

Kind regards
Lidka

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Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het informatiecentrum ...

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Dutch experts on climate change adaptation join forces. Fourteen Dutch knowledge institutes have joined forces to provide practical, demand-driven policy advice based ...

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Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het informatiecentrum ...

	Rijksinstituut voor Volksgezondheid en Milieu - RIVM www.rivm.nl Dutch experts on climate change adaptation join forces. Fourteen Dutch knowledge institutes have joined forces to provide practical, demand-driven policy advice based ...

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 6/22/2018 5:46:00 PM
To: Carter, Greg [Greg.Carter@icf.com]
CC: Soto, Vicki [Soto.Vicki@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Samuels, Crystal [Samuels.Crystal@epa.gov]; Kellar, Penelope [Penelope.Kellar@icf.com]; Ramasamy, Santhini [Ramasamy.Santhini@epa.gov]
Subject: work request Task 1 WA 4-17 - sending Formaldehyde main document
Attachments: Formaldehyde Main Text_techedit_062218.docx

Hi Greg and all,
Andrew and I have finished preparing the main document for tech editing. I'm sending it via email as we have been able to do this before, but let me know if you can't receive it. There may be a few comments for Andrew and I that you can ignore, but there are several pertaining to HERO or table/figure names etc that I hope you can address.

Thanks, Barbara and Andrew

Regulatory Toxicology and Pharmacology 81 (2016) 512–521

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

The need for transparency and reproducibility in documenting values for regulatory decision making and evaluating causality: The example of formaldehyde

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ARTICLE INFO

Article history:
Received 15 July 2016
Received in revised form
17 October 2016
Accepted 18 October 2016
Available online 19 October 2016

Keywords:
Reproducibility
Dose-response analysis
Formaldehyde
Inhalation unit risk estimates
Quantitative methods
Epidemiology

ABSTRACT

Reproducibility and transparency in scientific reporting is paramount to advancing science and providing the foundation required for sound regulation. Recent examples demonstrate that pivotal scientific findings cannot be replicated, due to poor documentation or methodological bias, sparking debate across scientific and regulatory communities. However, there is general agreement that improvements in communicating and documenting research and risk assessment methods are needed. In the case of formaldehyde, the peer-review conducted by a National Academy of Sciences (NAS) Committee questioned the approaches used by the Integrated Risk Information System (IRIS) in developing draft unit risk values. Using the original data from the key study (Beane Freeman et al., 2009) and documentation provided in the draft IRIS profile, we attempted to duplicate the reported inhalation unit risk values and address the NAS Committee's questions regarding application of the appropriate dose-response model. Overall, documentation of the methods lacked sufficient detail to allow for replication of the unit risk estimates, specifically for Hodgkin lymphoma and leukemias, the key systemic endpoints selected by IRIS. The lack of apparent exposure-response relationships for selected endpoints raises the question whether quantitative analyses are appropriate for these endpoints, and if so, how results are to be interpreted.

1. Introduction

Reproducibility and transparency in scientific research and reporting, both in the published literature and in documentation of decisions related to public health reached by authoritative bodies, have received significant discussion and debate (Bustin and Nolan, 2015; Campbell, 2014; Iqbal et al., 2016; Jilka, 2016). The National Institutes of Health (NIH) are exploring ways to provide greater transparency of the data that are the basis for published manuscripts (Collins and Tabak, 2014) and have noted that the greater scientific community must take steps to correct this issue. In addition, recent commentaries and surveys highlight the growing lack of reproducibility in scientific research (Anonymous, 2016). One of the most immediate and impactful consequences for a lack of transparency or reproducibility is in the direct reliance on published but un-replicated scientific findings for human health risk assessment, including the derivation of cancer unit risk estimates.

In 2011, the National Research Council (NRC) of the National Academy of Sciences (NAS) convened a Committee to Review USEPA's Draft of the *Toxicological Review of Formaldehyde – Inhalation Assessment* in support of the Integrated Risk Information System (IRIS) (NRC, 2011). The Committee noted:

> *"Problems with clarity and transparency of the methods appear to be a repeating theme over the years, even though the documents appear to have grown considerably in length"*

A further review of the IRIS process in 2014 (NRC, 2014) noted progress in meeting the NRC (2011) recommendations, but further noted:

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http://dx.doi.org/10.1016/j.yrtph.2016.10.011
0273-2300/

"However, NRC committees have conducted several reviews of some of the more complex and challenging IRIS assessments in the last decade and have identified methodologic problems and pointed out deficiencies in EPA's approaches."

Formaldehyde provides one such complex database that introduces significant challenges for consideration in a standard IRIS assessment. It is an endogenously generated compound and, for selected endpoints, multiple studies provide inconsistent results, a few of which have suggested associations with formaldehyde exposure. Some have interpreted these findings (generally at face value and apart from the larger body of results) as reflecting causal associations. As an example, there has been much scientific debate regarding whether there is a causal association between formaldehyde exposure and selected lymphohematopoietic (LHP) endpoints, especially acute myeloid leukemia. Multiple authoritative bodies (IARC, 2012; NTP, 2014) have made hazard classification decisions (sufficient evidence in humans, known to be a human carcinogen) based on conclusions that the available evidence is sufficient to conclude that there is a causal association. For the LHP cancers, these conclusions have been based on the grouping of different types of cancers from a limited number of epidemiological studies (Zhang et al., 2009; Beane Freeman et al., 2009), with little or no consideration of findings reported in many other studies or the animal or mechanistic information, much of which lends no support for or even contradicts these conclusions. It is important to note that in reviewing the same critical studies for formaldehyde as IARC (2012) and NTP (2014), the European Chemicals Agency (ECHA, 2011) concluded that

"Altogether, in absence of convincing evidence for a biologically plausible mechanism and considering the discrepancy of results in epidemiological studies, a causal relationship between formaldehyde exposure and induction of myeloid leukaemia cannot be concluded."

The 2010 draft IRIS *Toxicological Review of Formaldehyde – Inhalation Assessment* provided the first quantitative estimates of a dose-response relationship between two lymphohematopoietic endpoints, Hodgkin lymphoma (HL) and all leukemias (combined category), and exposure to formaldehyde based on the results from a single epidemiological study (Beane Freeman et al., 2009). The use of these two endpoints by USEPA (2010) for the estimation of unit risk factors was based on the conclusion that the weight of the epidemiologic evidence supported a link between formaldehyde exposure and LHP cancers, particularly myeloid leukemias. In addition to HL largely being considered unrelated to environmental exposures, no other key epidemiological study demonstrates such an association, raising questions as to the validity of the finding in Beane Freeman et al. (2009). As for the combination of all leukemias, little scientific basis is provided for aggregating what increasingly are understood to be diverse diseases with different etiologies, prognoses and treatments.

In 2011, the NRC Committee review noted many uncertainties in the approach used by USEPA (2010) to estimate risk values. The Committee recognized that USEPA (2010) had relied upon selected associations reported between formaldehyde and various LHP cancers from a single study (Beane Freeman et al., 2009). The NRC (2011) Committee further recommended that USEPA conduct an independent analysis of the dose-response models to confirm the degree to which the models fit the data appropriately, as well as consider the use of alternative extrapolation models for the analysis of the cancer data. The NRC (2011) Committee concluded that this is especially important, given the use of a single study, the inconsistencies in the exposure measures, and the uncertainties associated with the selected cancers. In addition to the impact of these assumptions, the NRC (2011) Committee noted that while the National Cancer Institute (NCI) cohort studies, including Beane Freeman et al. (2009), may be the only studies with sufficient exposure and dose-response data needed for risk estimation, they are not without weaknesses and these need to be considered. This recommendation from the NRC (2011) Committee raised several challenges. While there is some guidance provided for the use of animal data for dose-response modelling (USEPA, 2012), the use of epidemiological data in the estimation of inhalation unit risk (IUR) estimates does not have guidance that provides a "road map" for conducting these types of assessments. When using epidemiological data for the estimation of unit risk values, more extensive documentation in the IRIS profile is needed to be able to clearly understand the data relied upon and the methods applied.

In a separate study (Checkoway et al., 2015), the raw data from the NCI cohort study (Beane Freeman et al., 2009) were obtained through a Technology Transfer Agreement (TTA) with the objective of replicating the findings reported by Beane Freeman et al. (2009), as well as conducting additional analyses not reported by Beane Freeman, specifically, acute myeloid leukemia (AML). The availability of these data provided an opportunity to attempt to replicate the unit risk estimates derived by USEPA (2010), as well as address some of the questions raised by NRC (2011). In addition, it offered the opportunity to conduct alternate independent analyses to evaluate specific leukemias, rather than all leukemias combined, and the impact of alternate dose-response models on the estimates of inhalation unit risk. The methods and results of the attempt to duplicate the USEPA (2010) unit risk values, as well as conduct alternate and independent analyses to address the questions raised by NRC (2011) are reported here.

2. Methods

2.1. Duplication of USEPA (2010) reported unit risks

Our goal was to follow the same process and methods used by USEPA (2010) in the estimation of unit risk factors for the two LHP cancers (Hodgkin Lymphoma and all leukemias (combined category)). However, as noted by NRC (2011), the documentation provided in USEPA (2010) related to the assumptions and processes used in the estimation of the unit risk values was limited. NRC (2011) has outlined five steps that it appears USEPA (2010) used in the estimation of formaldehyde unit risks:

1. Evaluate the association between formaldehyde exposure and LHP endpoints;
2. Convert the relative risk estimates into lifetime risk for the exposed population;
3. Compute lifetime risks for Hodgkin Lymphoma and/or all leukemia for the unexposed population;
4. Determine the maximum likelihood and lower bound estimates of the point of departure; and
5. Estimate inhalation unit risks.

Using these five steps, we attempted to duplicate the USEPA (2010) reported unit risks for Hodgkin lymphoma and "all leukemias" using the raw data from the Beane Freeman et al. (2009) study. In order to conduct this estimate, the following were needed:

- *An estimate of cumulative dose for each individual in the cohort.* This information was not provided in either USEPA (2010) or Beane Freeman et al. (2009) and must be determined from the raw data.

- *Person time at risk for each individual.* Also not provided in USEPA (2010) or Beane Freeman et al. (2009) and must be determined from the raw data.

Absent this necessary information and with no data available to confirm how it was used in estimating risk, assumptions were necessary that impact the estimation of parameters characterizing the relationship between dose and response.

NRC (2011) also recommended that the evaluation of the epidemiological data focus on the most specific diagnoses available. Based on this recommendation, analyses were conducted to include the consideration of individual LHPs rather than combination of endpoints (e.g. all leukemias) and evaluation of alternate dose-response models for these individual endpoints. While the impact of dose metric selection (e.g., 'peak'[1] versus cumulative) has been a point of discussion in interpretation of the NCI cohort (Checkoway et al., 2015), specifically the lack of actual peak measures or estimates, the USEPA (2010) has noted that cumulative exposure is generally the preferred metric for quantitative risk assessment and was relied upon for the estimation of unit risk values. Therefore, the analyses reported below focused on cumulative exposure estimates based on the data obtained through the TTA and reported in Beane Freeman et al. (2009) and Checkoway et al. (2015).

2.2. Evaluation of model selection

NRC (2011) noted that information was needed on the degree to which the model used (i.e., Poisson regression model) fits the data, especially for dose-response analysis. NRC (2011) further noted that this type of analysis is essential because dose-response models for risk estimation must fit the data well in the low-dose range and alternative extrapolation models, including Cox regression models and nonlinear model forms, should be considered in order to identify the best-fitting model. We conducted additional analyses to evaluate the potential impact of NRC (2011) comments on both the methods and the data relied upon for unit risk estimation, as well as consideration of multiple models. In addition to a Poisson regression model, the logistic regression model was considered, as well as a Cox regression model that was applied to the data from Beane Freeman et al. (2009) by Checkoway et al. (2015). All models used a 2-year lag for exposure, which is consistent with a lag considered by both Beane Freeman et al. (2009) and Checkoway et al. (2015).

A log-linear Poisson model, which is the model reported by Beane Freeman et al. (2009) to estimate the exposure-response relationship (β values), was used to compare the results in this analysis to the results published in Beane Freeman et al. (2009) in which the cumulative 2-year lag exposure variable was categorized into discrete exposure variables using the 4 categories reported (0 ppm-years, >0 and < 1.5 ppm-years, ≥1.5 and < 5.5 ppm-years, and ≥5.5 ppm-years). A log-linear Poisson model was also fit using the discrete dose categories reported by Checkoway et al. (2015) (<0.5 ppm-years, ≥0.5 and < 2.5 ppm-years, and ≥2.5 ppm-years). In addition, both a log-linear Poisson model and a logistic regression model were fit to the data using a categorization scheme for the 2-year lag cumulative dose that split the data into quartiles so that an approximately equal number of subjects were in each group (<0.05 ppm-years, ≥ 0.05 and < 0.4 ppm-years, ≥0.4 and < 2.4 ppm-years, and ≥2.4 ppm-years). All models were run considering person-time at risk, sex and race and adjusted for pay type (i.e., hourly vs. salary). For the logistic and Poisson models, quadratic terms for exposure were also considered. For evaluation of potential model fit to the data in the low concentration region, a visual examination of the Poisson and log-logistic model estimates were compared to the case status at the end of follow-up for each individual, again considering person-time at risk, sex, race and pay type.

[1] The 'peak' exposure metric used in Beane Freeman et al. (2009) is a relative peak estimator described in Stewart et al., 1986.

3. Results

3.1. Duplication of USEPA (2010) reported unit risks

3.1.1. Step 1 – evaluate the association between formaldehyde exposure and LHP endpoints

The attempt to estimate the unit risks reported in USEPA (2010) was initiated using the model parameters (β parameters from the log-linear Poisson regression model) provided to USEPA via personal communication by Dr. Laura Beane Freeman. The β parameters describe the relationship between exposure and response. Prior to estimating the unit risk, using the raw data, we attempted to replicate the model parameter estimates provided to the USEPA (2010) by Dr. Beane Freeman using log-linear Poisson regression, which is the same modelling approach reported to have been used to develop these estimates in both the Beane Freeman et al. (2009) publication and in the draft IRIS evaluation (USEPA, 2010) (Table 1). In addition, Cox and logistic regression models were considered.

Since cumulative exposure was the focus of the USEPA (2010) unit risk estimates, an initial analysis to evaluate the association between this exposure metric and the two endpoints relied upon for unit risk estimates (i.e., Hodgkin lymphoma and all leukemias combined) was conducted. Several variables were needed from the raw data, including the estimate of cumulative exposure (ppm) for each individual and person time at risk for each individual, neither of which are provided in USEPA (2010) or Beane Freeman et al. (2009) and had to be estimated from the raw data. In addition, in order to estimate the β parameters, the raw data regarding the number of deaths from a specific cancer and corresponding exposure metric must be divided into the same exposure quartiles as those reported by Beane Freeman et al. (2009) to evaluate the exposure-response relationship.

For the current analyses, the following steps were conducted to identify the data needed for analysis.

1. Using the work history data and date of birth, the data records were combined and organized to result in one or more record for each job so that no record spanned a calendar year or a change in age. Calculation of the duration of each work record was performed in this step with consideration of leap years. Since only start and stop months of work were provided in the raw data from Beane Freeman et al. (2009), the initial start and final stop day for a job were assumed to be the 15th of the month unless the start and stop months were the same month in the same year. In this case, the stop day was assumed to be the appropriate value for the end of the month (28, 29, 30 or 31). The gender, race, salary code and status of each individual (alive or dead) and cause of death ICD code were also attached to the individual's record.
2. The exposure and duration of exposure were summed over the months in a year when the individual was a specific age. During this step, the peak exposure category for each work record was determined.
3. The cumulative and lagged cumulative exposure and person-years of exposure were calculated.
4. The records were categorized into the strata of ranges of years (groups covering a 5 year period starting with 1960 and ending

Table 1
Comparison of modelling statistics from the current analysis to statistics reported in USEPA (2010).

	Current analysis												USEPA (2010)		
	Cox regression			Logistic regression					Poisson regression						
	p-value [a]	β (per ppm x year)	Standard error (per ppm x year)	R^2	LR p-value[b]	p-value [a]	β (per ppm × year)	Standard error (per ppm × year)	LR p-value[b]	p-value [a]	β (per ppm × year)	Standard error (per ppm × year)	p-value	β (per ppm × year)	Standard error (per ppm × year)
Hodgkin lymphoma (201)	0.013	0.0294	0.0119	0.0133	0.098	0.019	0.0288	0.0123	0.09	0.037	0.0243	0.0117		0.02959	0.01307
Leukemia (204–207)	0.058	0.0117	0.0062	0.0017	0.35	0.055	0.0121	0.00628	0.003	<0.001	0.0206	0.0057	0.08	0.01246	0.000642
Leukemia (204–207, excluding 204.1)	0.239	0.0092	0.0079	0.0011	0.64	0.206	0.01	0.00791	0.034	0.013	0.018	0.0073	–	–	–
Acute myeloid leukemia (205.0)	0.844	−0.004	0.0201	0.0016	0.82	0.869	−0.0032	0.0196	0.81	0.80	0.0045	0.0179	–	–	–

Cox regression model $h(t,x) = h_0(t)\ exp(\beta x + \gamma z)$.
Logistic regression model $Y = 1/[1 + exp(-\alpha + \beta x + \gamma z)]$.
Poisson regression model $Ln(Y/t) = \alpha + \beta x + \gamma z$ OR $Y = t\ exp(\alpha) \times exp(\beta x)) \times exp(\gamma z)$.
Where Y is the expected number of events, α is the intercept, β is the slope term, x is the exposure, z is a covariate and t is the duration of exposure. In the Cox model h is the hazard rate.

[a] These p-values reflect the precision of any association between exposure and response, and show the probability that the beta value is not significantly different from zero. P-values < 0.5 indicate that the beta parameter is significantly different from zero.

[b] The likelihood ratio p-values of difference between a null and dose-dependent model (e.g. test of β = 0) where small p-values reject the hypothesis that β = 0.

with 2010), and age groups (groups covering a 5 year range starting with the age of 15 and ending with 85), where the lowest year group included all records prior to 1965, and the 1965 group included years 1965 through 1969, with all job records occurring in 2010 and after included in the 2010 category. For ages, all ages less than 20 were included with the 15 year old age group, and the second group labelled 20 included all ages from 20 through 29.

5. The final record for each individual included an indication of dead or alive. For those individuals who had died, the ICD codes were used to set up yes/no flags indicating whether Hodgkin lymphoma, leukemia or acute mylogenous leukemia were found in that individual.

This process resulted in 1,047,291 work records that were then used in the analyses. All analyses used stratification for age group, year group, gender and race, with all the models adjusted for salary type treated as a classification variable. The Poisson analysis (SAS Proc Genmod) used a Poisson distribution, a log link and an offset of the natural log of the cumulative person-years of exposure. SAS Proc Logistic was used to perform the logistic regression and Cox proportions hazards models were performed using STATA (Checkoway et al., 2015).

Beane Freeman et al. (2009) reported that the cut points for the exposure groups were based on the approximate 60th and 80th percentiles from the cumulative exposures for those subjects with cancer. In attempting to duplicate the number of cancers within each exposure group, the cut points of 1.5 and 5.5 ppm-years (cumulative exposure groups defined by Beane Freeman et al. (2009) as ≤0 to 1.5, 1.5 to <5.5, ≥5.5 ppm-years) could not be duplicated based on the estimated 60th and 80th percentiles using the raw data. The calculations for the current assessment resulted in the determination of 1.2 and 4.2 ppm-years as the 60th and 80th percentiles for the cumulative exposure of the subjects with cancer. In addition, the number of unexposed workers (4359) reported by Beane Freeman et al. (2009) could not be replicated. Using the raw data, only 2676 unexposed workers could be identified.[3]

Regardless of the lack of ability to duplicate this determination of exposure, an evaluation of the exposure-response relationship was conducted. For the "all leukemia" category, exposure-response was evaluated including and excluding chronic lymphocytic leukemia (CLL), because, as noted by Checkoway et al. (2015), CLL has been classified as a non-Hodgkin lymphoma (NHL) since 2001 (Muller-Hermelink et al., 2001; Campo et al., 2011).

Other models were attempted in this process. Using quadratic terms for exposure failed to provide any better fit of the models to the data. In addition, the effect of exposure to other substances were explored but these did not improve the model fits substantially, either.

As noted in Table 1, in attempting to duplicate the β parameter and standard error for each cancer type, similar values could be estimated, but the estimates reported in USEPA (2010) could not be duplicated, which can impact attempting to duplicate unit risk estimates. In addition, it is important to note that no significant association between leukemia as a class of diseases (p-values > 0.05; Table 1) or specifically for acute myeloid leukemia ($p \geq 0.8$) with cumulative exposure to formaldehyde was found (using the typical 0.05 as the determinant of "significant") for either the Cox regression or the logistic regression. In addition, the estimated β parameter for acute myeloid leukemia (~-0.004 from the Cox regression and the logistic regression) indicates that the slope is in the negative direction (decreasing incidence with increasing exposure). These results for AML suggest that it would not be appropriate to rely upon these negative data independently in the dose-response modelling for the estimation of a unit "protection" estimate. As imprecise positive estimates of a β parameter should not be interpreted as evidence of risk, imprecise negative β parameters should not be interpreted as beneficial or protective. For all the logistic models, the likelihood ratio test indicates that the β parameter is not statistically different from zero. Similarly the likelihood ratio test of the Poisson models for Hodgkin lymphoma and the acute myeloid leukemia also indicate that the β parameter is not statistically different from zero. Only for the Poisson models of combined leukemias are the β values considered to be statistically significantly different from zero. However, as these are

combined types of leukemia which are not recommended by the NRC (2011) and there is almost a factor of 2 difference between the β estimates between the different models in the current analysis and the USEPA (2010) β estimate, there is still large uncertainty in the results.

The estimated β parameter for Hodgkin lymphoma was comparable to that reported in USEPA (2010); however, there was a difference in the standard error and a larger difference in the p-values. USEPA (2010) reported a non-significant trend between cumulative formaldehyde exposure and Hodgkin lymphoma based on information reported in Beane Freeman et al. (2009), while the current analysis suggested a significant trend (p-value = 0.013). These results are consistent with those reported by Checkoway et al. (2015). However, Checkoway et al. (2015) notes that the increased risk of HL has not been observed in other occupational studies of formaldehyde-exposed cohorts, and is not regarded as plausibly related to environmental chemical exposures.

Because the β parameters could not be duplicated, it was concluded that while additional steps could be conducted to evaluate the transparency of the process, the lack of ability to duplicate this first step would result in a lack of ability to duplicate the reported unit risks. Even having access to the raw data from the Beane Freeman et al. (2009) study, there were not enough details regarding the methods used to evaluate the data provided in USEPA (2010) to duplicate the initial β parameters necessary to initiate the unit risk estimate process.

3.1.2. Step 2 – convert the relative risk estimates into lifetime risk for the exposed population

Relying strictly on the β parameters reported in USEPA (2010), even though they could not be duplicated, an attempt was made to conduct the remaining steps of the estimation of unit risk as outlined by NRC (2011). USEPA (2010) noted that the β parameters were used in a life table analysis to calculate lifetime extra cancer risks from formaldehyde exposure. This step, as well as step 3, requires the use of a life-table method in conjunction with (a) the Poisson model mortality risk, (b) age-specific all-cause mortality rate in the United States population, and (c) Hodgkin lymphoma and all leukemia mortality rates, all of which can be derived from the NCI's Surveillance, Epidemiology and End Results (SEER) database. SEER collects cancer incidence data from multiple geographical areas in the United States. This step also requires estimates of the effective concentration (EC) for occupational exposure adjusted to continuous ambient exposure (the standard exposure metric relied upon by USEPA in the estimation of a unit risk) by multiplying by the ratio of days in a year to work days (240, 50 weeks of 5 day work weeks) and the ratio of daily inhalation rate (20 m^3) to work day inhalation rate (10 m^3) (USEPA, 2010).

$$EC = exposure\ (ppm) \times \frac{365}{240} \times \frac{20}{10}$$

USEPA (2010) provided a spreadsheet (Appendix C of USEPA, 2010; Supplemental Tables S1 and S2) illustrating the life table used for the extra risk calculation for the derivation of the LEC_{0005} (95% lower confidence limit on the effective concentration corresponding to an extra risk of 0.05%) relied upon for estimating the IUR based on nasopharyngeal (NPC) mortality reported by Hauptmann et al. (2004). USEPA (2010) noted that the same general methodology described for NPC mortality estimates was used for Hodgkin lymphoma and leukemias, with the following exceptions:

- U.S. age-specific 2006 all-cause mortality rates (NCHS, 2009);
- NCHS age-specific 2002–2006 background mortality rates for Hodgkin lymphoma and leukemia (http://seer.cancer.gov/csr/1975-2006/) for all race and gender groups; and
- A 2-year lag period instead of a 15-year lag period.

It is important to note that USEPA (2010) provided no citation for the NCHS (2009) all-cause mortality rates, so it was assumed this was obtained from the NCHS website (http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf) as the background mortality rates for specific cancers (Heron et al., 2006). While this does provide data needed to allow the assessor to attempt to duplicate this procedure, there is no comparable life-table for Hodgkin lymphoma or all leukemias to ensure that comparable results are achieved. Relying upon these sources and following these approaches, the IURs provided in USEPA (2010) could not be duplicated using the reported sources and methodology. This was also true for NPC for which the life table was provided (Appendix C; USEPA (2010)). In attempting to duplicate the IURs reported for NPC, it was determined that the values reported from the use of the life table instructions provided could not produce the reported IURs for NPC (see supplemental Table S1 for the re-creation of the calculations that would correspond to the unit risks reported in USEPA (2010) when using the instructions provided by USEPA (2010) for Table C-1. The difficulty in duplicating the life table reported was related to the function reported for estimating the NPC incidence hazard rate (Column L in Supplemental Table 2). Using the USEPA (2010) β of 0.0518 (SE 0.01915) and the calculations as specified in Table C-1 of USEPA (2010), the estimated EC_{0005} and LEC_{0005} would be 0.103 and 0.0623 ppm, respectively, with a unit risk of 8×10^{-3}. However, the calculations specified in Appendix C of USEPA (2010) indicated a function for the hazard incidence rate of $hx_i = h_i \times (1 + \beta \times xdose)$ which is inconsistent with the model of risk that was used to determine the β value ($RR = e^{\beta X}$, where β represents the regression coefficient for exposure and X is exposure as a continuous variable) (USEPA, 2010). When the hazard rate function is changed to $hx_i = h_i \times (e^{\beta \times xdose})$ to properly reflect the underlying risk function, the values estimated by the revised life table were the same as those reported by the USEPA in Tables 5–11 for EC_{0005} and LEC_{0005} based on NPC incidence for formaldehyde exposure (0.074 and 0.046 ppm, respectively, see supplemental Table S3 for the adjusted life-table calculation). However, it is important to note that these estimates rely upon the β parameters reported in USEPA (2010), which cannot be duplicated.

3.1.3. Step 3 – compute lifetime risks for Hodgkin Lymphoma and/or all leukemia for the unexposed population

As noted in USEPA (2010), USEPA cancer risk estimates are typically derived to represent a plausible upper bound on increased risk of cancer *incidence*, typically based on experimental animal incidence data. However, epidemiological studies more often present results based on mortality data, which is true for the Beane Freeman et al. (2009) study. For cancers with low survival rates, mortality-based estimates are a reasonable approximation of cancer incidence risk. However, USEPA (2010) largely documents its approach to the evaluation of nasopharyngeal cancers and noted the need to estimate incidence-based risks. Estimation of the incidence of a particular cancer type using mortality data can be conducted by acquiring the age-specific incidence rates for a specific cancer from the SEER program. In order to estimate the potential risk of incidence of a cancer type, the data from the SEER database are used to adjust the mortality data assuming that the exposure-response relationship for incidence and mortality of a cancer type are the same. An examination of the assumptions and adjustments made to the Beane Freeman et al. (2009) data for lymphohematopoietic cancers follows.

Table 2
Extra risk estimates for Hodgkin lymphoma mortality from various levels of continuous exposure to formaldehyde (reproduced from Tables 5–14 in USEPA (2010)).

Exposure concentration (ppm)	As reported by USEPA (2010)		Estimated using the life table provided in USEPA (2010) [a] with adjustments to the hazard function	
	Extra risk	95% UCL on extra risk	Extra risk	95% UCL on extra risk
0.0001	2.04×10^{-7}	3.53×10^{-7}	2.52×10^{-7}	4.36×10^{-7}
0.001	2.05×10^{-6}	3.55×10^{-6}	2.53×10^{-6}	4.38×10^{-6}
0.01	2.10×10^{-5}	3.71×10^{-5}	2.59×10^{-5}	4.59×10^{-5}
0.1	2.79×10^{-4}	6.17×10^{-4}	3.44×10^{-4}	7.63×10^{-4}
1	1.63×10^{-1}	8.36×10^{-1}	1.90×10^{-1}	8.53×10^{-1}
10	9.89×10^{-1}	9.90×10^{-1}	9.89×10^{-1}	9.90×10^{-1}

[a] Using the supplied information in the life table provided in USEPA (2010) with an adjustment in column L for the incidence hazard rate in interval I ($hxi = hi \times e^{(\beta \times xdose)}$) for the estimates of $\beta = 0.02959$, SE = 0.01307.

Table 3
Extra risk estimates for leukemia mortality from various levels of continuous exposure to formaldehyde (reproduced from Tables 5–15 in USEPA (2010)).

Exposure concentration (ppm)	Calculated by USEPA (2010)		Estimated using the life table provided in USEPA (2010) [a] with adjustments to the hazard function	
	Extra risk	95% UCL on extra risk	Extra risk	95% UCL on extra risk
0.0001	1.64×10^{-6}	3.02×10^{-6}	1.65×10^{-6}	3.06×10^{-6}
0.001	1.64×10^{-5}	3.03×10^{-5}	1.65×10^{-5}	3.07×10^{-5}
0.01	1.66×10^{-4}	3.10×10^{-4}	1.67×10^{-4}	3.13×10^{-4}
0.1	1.87×10^{-3}	3.90×10^{-3}	1.89×10^{-3}	3.95×10^{-3}
1	8.07×10^{-2}	5.19×10^{-1}	8.16×10^{-2}	5.28×10^{-1}
10	9.80×10^{-1}	9.89×10^{-1}	9.80×10^{-1}	9.89×10^{-1}

[a] Using US 2006 mortality rates, the adjusted life table structure and potency estimates ($\beta = 0.01246$, SE = 0.006421) from USEPA (2010).

Table 4
Relative risk based on peak exposure from Poisson model stratified by calendar year, age, sex and race and adjusted for pay category.

	0 ppm		>0 to <2.0 ppm		> = 2.0 to <4.0 ppm		> = 4.0 ppm		Log likelihood	p-value
Total in group	3139		10,302		6010		6168			
Person-years	104,386		415,987		254,723		256,618			
	Cases	RR (95% CI)	Cases	RR (referent)	Cases	RR (95% CI)	Cases	RR (95% CI)		
Hodgkin lymphoma (201)	2	3.32 (0.60–18.26)	6	1.0	8	0.76 (0.30–1.89)	11	2.96 (0.94–9.27)	−309.87	0.04
Leukemia (204–207)	7	1.83 (0.76–4.40)	41	1.0	27	0.58 (0.36–0.93)	48	0.58 (0.36–0.93)	−1177.94	0.004
Leukemia (204–207, excluding 204.1)	6	1.61 (0.61–4.24)	28	1.0	20	0.56 (0.32–0.96)	37	1.17 (0.65–2.09)	−901.65	0.009
Acute myeloid leukemia (205.0)	4	1.21 (0.33–4.43)	9	1.0	9	0.77 (0.32–1.84)	12	1.72 (0.67–4.43)	−374.47	0.34

Since USEPA's life table analysis relied upon background mortality rates to determine the extra risk from the incidence of the endpoint of interest, the effect of using background incidence data for Hodgkin lymphoma and all leukemia was explored. The background mortality rates were adjusted to reflect the background incidence of the endpoint by replacing the mortality rate attributed

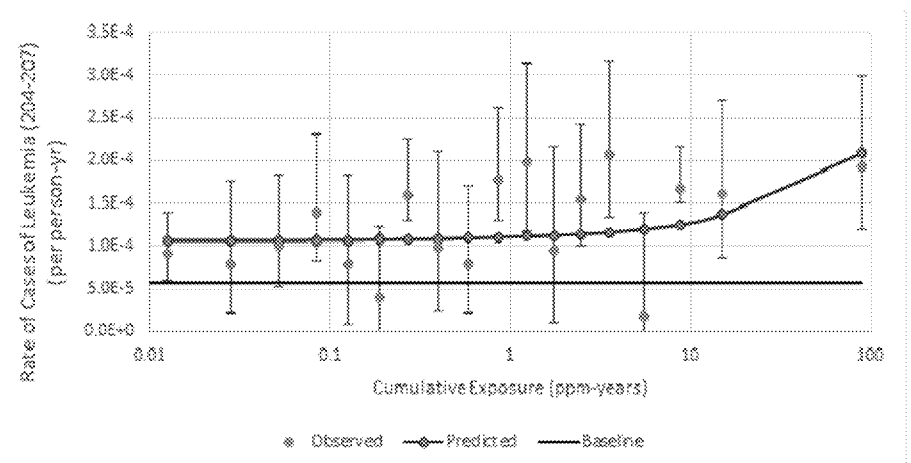

Fig. 1. Comparison of estimated cases from the Poisson regression model to number of cases of leukemia observed at the end of follow-up period in the Beane Freeman et al. (2009) study. Observed and predicted results over full observed exposure range.

to that endpoint with the incidence rate of that endpoint. Making this correction resulted in a difference of between 10 and 21% in the estimated risks for the current analysis.

3.1.4. Step 4 – determine maximum likelihood and lower bound estimates of point of departure

USEPA's carcinogenicity risk-assessment guidelines (USEPA, 2005) recommend the use of an extra risk of 1–10% for deriving effective concentration at the Point of Departure (POD), or for the USEPA (2010) IRIS assessment. NRC (2011) noted that in USEPA (2010) there was an unusual choice of a 0.05% extra risk for Hodgkin lymphoma and 0.5% extra risk for all leukemias. USEPA (2010) noted the issues with using standard extra risk levels (e.g., 10%) in that the risks using these standard extra risk assumptions resulted in relative risk estimates that were substantially higher than those observed in the epidemiology study. Therefore, the choice of the extra risk value to use was based on the background mortality rate for each individual cancer type compared to the relative risk estimates observed in the Beane Freeman et al. (2009) study. Relative risk estimates were determined starting at the 10% extra risk level, decreasing the extra risk level until the relative risk estimates were within the observable range of the epidemiology study. For example, if the 1% level of risk associated with the relative risk estimates for NPC were higher than those observed in the Beane Freeman et al. (2009) study, the extra risk level of concern was lowered until the relative risk estimates were below the relative risk estimates from the Beane Freeman et al. (2009), so an upward extrapolation could be conducted. This approach effectively assumes that nothing observed in the Beane Freeman et al. (2009) could be attributable to background incidence of these cancer types.

Using the hazard rate function as instructed in the life table example (Footnote for Column L, Table C-1 of USEPA (2010)), the extra risk and 95% upper confidence limits on extra risk provided in USEPA (2010) cannot be reproduced (Tables 2 and 3). However, using a life table that had a hazard rate function consistent with the underlying risk function produced results that were similar to those reported by the USEPA (2010). Supplemental Tables S2 and S4 show the differences in the risk values calculated at an exposure of 1 ppm using the USEPA (2010) instructions (Table S2) versus the revised life table (Table S4) with the modified hazard function that was necessary to duplicate the EC, LEC and unit risk values reported in USEPA (2010). While there was some correspondence, there were still some differences in the values that were calculated for the extra risk (Tables 2 and 3) and there is some concern about the appropriateness of the risk estimates, especially large estimates of risk for values above 0.1 ppm. An exposure of 0.1 ppm is within the range of exposures (0.01–4.3 ppm – TWA) reported by Beane Freeman et al. (2009). The relative risk values estimated for these exposures approach 100% and are inconsistent with the observed incidences of cancers in the Beane Freeman et al. (2009) study.

3.1.5. Step 5 – convert the relative risk estimates into lifetime risk for the exposed population

With the results from step 4, the lower bounds on exposure (LECx) and the extra risk level should then be used to determine the unit risks. However, because the model parameters from step 1 could not be replicated, an attempt was made to replicate the MLE and lower bounds using the USEPA (2010) reported model parameters. Using a life table analysis that follows the methods provided in Appendix C of USEPA (2010) and the reported model parameters, the MLE and lower bounds on dose for Hodgkin lymphoma and all leukemia could not be replicated. Using the available parameters and results reported in USEPA (2010) and using the USEPA's parameters, a 12–27% difference in unit risk values was determined for leukemia, Hodgkin's lymphoma and NPC from those reported by the USEPA (2010). However, when the life table was adjusted to be consistent with the relative risk model that was the basis of the β value used in USEPA (2010), the values reported by the USEPA could be replicated.

In noting the potential differences in unit risk estimation, this 12–27% difference could be considered in combination with the potential differences in unit risk from step 1 (differences in the model results), as well as the potential impact of the differences in risk from step 3. Therefore, the inability to replicate individual steps in the process may result in unit risk estimates different from those in USEPA (2010) by 100% or greater due to differences in the slope factors (up to 100% difference) as well as differences in life table analysis results (12–27%) that would be calculated following the documentation provided in USEPA (2010).

Analyses were also conducted using the "peak" exposure metric, rather than the continuous metric relied upon by USEPA (2010) for their evaluation. This was conducted using the same model (log-linear Poisson stratified by calendar year, age sex, and race and adjusted for pay category) as Beane Freeman et al. (2009), but in contrast to the results reported by Beane Freeman et al. (2009), no significant relative risks were estimated (Table 4). Reasons for the differences between the current analyses and those reported by Beane Freeman et al. (2009) could include that the specific dates of job start and job end were not provided, nor were the specific dates that follow-up started or ended: only month and year were reported.

3.1.6. Evaluation of model selection

In evaluating the potential fit of the model to the data, there are various tests that can be performed to look at the predictive power of a model (e.g. R^2 tests, χ^2 tests), to make comparison between models (e.g. AIC and other log-likelihood tests) or graphical representations of the data to visualize the fit. However, since no such statistics were provided in either Beane Freeman et al. (2009) or USEPA (2010), comparisons can only be made among the models fit to the data in this current analysis. The R^2 values reported for the logistic regression performed in this analysis were uniformly poor (i.e., 0.05 or less) indicating poor predictive ability of the models. For the Poisson models, there were small values for the Pearson χ^2 value which, with the large sample size, achieved a better fit to the data (p-values close to 1). However, in graphs presented in this analysis using the data at the end of follow-up, the rate of all leukemias was plotted against the continuous exposure as well as the model predicted rates estimated for both the Poisson regression model (Fig. 1) and the logistic model (Fig. 2).[2] These figures show large variability in the observed rates in the low concentration region which subsequently makes comparison and evaluation of the fit of the model to the data difficult. This variability also makes any predictions made with models fit to these data highly uncertain. In addition, the predictions of extra risk provided by USEPA (2010)

[2] The graphs were constructed using the 5% percentiles (e.g. 5%, 10%, 15%, etc.) of the cumulative exposure, and sums of the person-years, number of individuals and number of observed and predicted leukemias per percentile to determine the rates. The confidence limits for the logistic graph were calculated using binomial confidence limits on the observed rates of leukemia per percentile group of exposure, and the Poisson confidence limits are exact confidence limits based on the Poisson distribution.

[3] This number of unexposed workers identified in the current analysis (2676) is consistent with the number determined by Checkoway et al. (2015) in a separate reanalysis of the raw data from Beane Freeman et al. (2009) study. When this difference was discovered by Checkoway et al. (2015), communications with Dr. Beane Freeman indicated that the number of unexposed workers reported was a mistake and should have been 3,108. However, Checkoway et al. (2015) could not duplicate this number of unexposed workers either using the raw data.

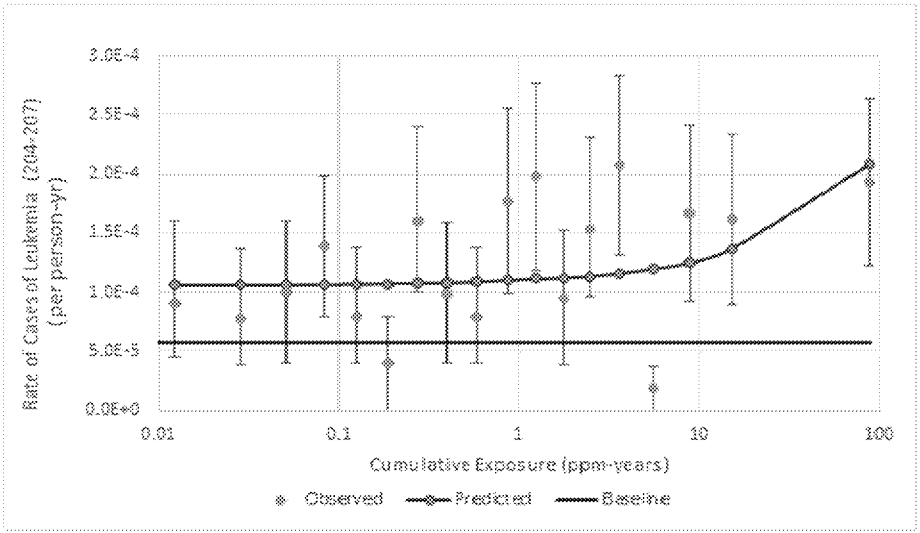

Fig. 2. Comparison of estimated cases from the logistic regression model to number of cases of leukemia observed at the end of follow-up period in the Beane Freeman et al. (2009) study. Observed and predicted results over full observed exposure range.

associated with higher concentrations (1 and 10 ppm) are above the observable range and involve upward extrapolation. The results are estimates of extra risk approaching 1, which are unreasonable.

While each model provides predictions that "run through the middle" of the data, it is clear that neither model can adequately predict the exposure-response relationships or lack of pattern in the lower concentration region (Figs. 1 and 2), as the data in this region of the exposure-response curve appears to be comparable to random variation. In the low concentration region, the data lack a clear monotonic dose-response relationship, which may explain lack of a significant trend ($p = 0.08$) even for the combination of all leukemias. Overall, the models do not fit the pattern of exposure-response in the data. While the models appear to be more consistent with the data at concentrations greater than 10 ppm-years, this comparison is largely influenced by two data points. It is possible that this shape of the exposure-response curve may explain the unusual nonlinearities in the estimates of extra risk provided by USEPA (2010) (Tables 2 and 3). However, explaining this unusual exposure-response behavior is difficult due to the inability to duplicate the unit risk estimates provided in USEPA (2010).

4. Discussion

One of the greatest challenges in attempting to duplicate unit risk factors estimated by USEPA is attempting to duplicate those specifically based on epidemiological data. When USEPA has relied upon animal data for the estimation of unit risk values, even when the documentation provided is limited, there are guidelines available (USEPA, 2012) that provide specific steps and assumptions used by USEPA in the dose-response analysis of animal data. However, when epidemiological data are applied, there is not comparable guidance, and the necessary additional detail may not be provided in the IRIS documentation to allow for transparency and the ability to duplicate risk values.

In the case of formaldehyde, the draft IRIS toxicological review (USEPA, 2010) provided documentation largely on the estimation of IURs from the cases of NPC from the NCI cohort reported by Hauptmann et al. (2004), assuming that these methods could easily be extended in an attempt to duplicate values for lymphohematopoietic cancers provided in an update to the NCI cohort by Beane Freeman et al. (2009). The results from this assessment, in attempting to duplicate unit risk values for lymphohematopoietic cancers, demonstrate that this is not the case.

Difficulty in duplication of results from each step of the process of the estimates of IURs, following the steps as outlined by NRC (2011), started with the initial step that involved duplication of the β parameters from the log-linear Poisson regression model as provided by Dr. Laura Beane Freeman to the USEPA. In the initial step of the process, our results suggest no significant association between cumulative exposure to formaldehyde, which is the exposure metric relied upon by USEPA (2010) for the estimation of the IURs, and either all leukemias combined or acute myeloid leukemia specifically. This lack of association is directly relevant to evaluation of causality and should be considered earlier in the determination of what endpoints likely are caused by exposure to formaldehyde and therefore which associations might be relied upon for the estimation of IURs. Based on the results for all leukemias, as well as AML, with no significant trends observed, it is not appropriate to conduct dose-response modelling only on null findings. In addition, while similar, the β values could not be duplicated even with the availability of the raw data, which suggests that the methods applied are not adequately documented in USEPA (2010).

USEPA (2010) relied heavily upon the Beane Freeman et al. (2009) study for risk estimation associated with lymphohematopoietic tumors, with the NRC (2011) committee noting that this may be the only study with sufficient exposure and dose-response data needed for risk estimation. However, they also noted that this study is not without weaknesses and these need to be considered. A reanalysis of the raw data from the NCI study (Beane Freeman et al., 2009) was conducted by Checkoway et al. (2015). While basic results were replicated, additional analyses of the associations of specific lymphohematopoietic cancers, specifically acute myeloid leukemia (AML) with various metrics of formaldehyde exposure (peak, average, cumulative) and using a more standard definition of peak exposure than that relied on by Beane Freeman et al. (2009) were reported. The re-evaluation highlighted many of the limitations in the data from this cohort, and the new analyses indicated no clear association with AML. It is not clear why AML results had not been reported in any of the updates of this study, and not considered in the IRIS evaluation, given that AML has been highlighted as the lymphohematopoietic cancer most likely to be

relevant to a chemical agent, primarily based on its association with benzene.

The results from the current analysis for Hodgkin lymphoma also provide estimates inconsistent with those reported by USEPA (2010). Using the cumulative exposure metric, USEPA (2010) reported no significant trend for Hodgkin lymphoma. The current analysis suggests a significant trend (Table 1 – $p = 0.013$), which is consistent with the results from Checkoway et al. (2015) reporting increased relative risk estimates for Hodgkin lymphoma in the highest exposure categories of cumulative and peak exposures. As noted in Checkoway et al. (2015), these findings are complicated because there is little epidemiological support for chemical exposures in the etiology of Hodgkin's lymphoma. There is an absence of an increased risk for this cancer type in other occupational cohorts, as well as the lack of a plausible biological mechanism. In addition, NTP (2014) noted that because the evidence for Hodgkin lymphoma is mainly limited to the NCI cohort study, a causal association is not established. As with all leukemias, including AML, there are questions related to a causal association between cumulative formaldehyde exposure and this cancer type that suggest that the estimation of a quantitative measure of risk using these data are inappropriate.

NRC (2011) also highlighted that the modes of action for formaldehyde-induced Hodgkin lymphoma and for leukemias have not been established. Moreover, the studies that demonstrate the lack of systemic delivery of formaldehyde following inhalation exposure (Lu et al., 2011; Moeller et al., 2011; Edrissi et al., 2013; Yu et al., 2015) draw into question the biological plausibility of formaldehyde causing any LHP cancer. NRC (2011) noted that

> *"Although EPA postulated that formaldehyde could reach the bone marrow either as methanediol or as a byproduct of nonenzymatic reactions with glutathione, numerous studies described above have demonstrated that systemic delivery of formaldehyde is highly unlikely at concentrations below those which overwhelm metabolism according to sensitive and selective analytic methods that can differentiate endogenous from exogenous exposures."*

Thus, substantial uncertainties remain in using both Hodgkin lymphoma and leukemias (all or individual) for consensus cancer risk estimation. Formaldehyde is rapidly metabolized and highly reactive and, because it is an endogenous compound, a detectable change in the natural background or endogenous levels would need to occur in order to result in the potential for adverse effects. Multiple studies using multiple species, including non-human primates, have been conducted using a sensitive analytical method that can measure endogenous versus exogenous formaldehyde DNA adducts (Yu et al., 2015; Edrissi et al., 2013; Moeller et al., 2011; Lu et al., 2011). The results of these studies indicated that inhaled formaldehyde was found to reach nasal respiratory epithelium, but not other tissues distant to the site of initial contact. These results suggest a lack of an ability for exogenous or inhaled formaldehyde exposure to affect endogenously present concentrations of formaldehyde.

Although the Draft Review cites hypotheses proposed by Zhang et al. (2010) regarding the theoretical development of leukemia following inhalation of formaldehyde, there is no documented evidence to support the validity of these hypotheses. In fact, Zhang et al. (2010) note that their hypotheses related to mechanisms of leukemia clearly require additional testing. The existing mechanistic data for formaldehyde provide no evidence that exogenous formaldehyde will be transported from the point of contact to distant sites, but do provide evidence that formaldehyde does not affect the relevant target cells for leukemia (bone marrow or peripheral blood) (Yu et al., 2015; Edrissi et al., 2013; Moeller et al., 2011; Lu et al., 2011).

Overall, the documentation of the methods applied by USEPA lacks sufficient transparency and detail for duplication of the unit risk estimates provided in USEPA (2010), even with the availability of the raw data from the Beane Freeman et al. (2009) study that USEPA relied upon for estimation of the risk of Hodgkin lymphoma or all leukemias. This lack of transparency and detail may result in different estimates of unit risks, including invalid estimates, especially as initial analyses resulted in a lack of a significant dose-response relationship for selected endpoints.

In attempting to duplicate the USEPA (2010) calculations, difficulties were encountered at each step, largely due to a lack of critical information provided in the IRIS documentation. Even though analyses were conducted multiple times with different assumptions, all of which could be consistent with the description provided by USEPA (2010), the unit risk values could not be duplicated. The results of the analyses yielded conflicting and different estimates with each step of the analysis, with differences in each step up to a factor of 2. The inability to replicate individual steps in the process may result in unit risk estimates different from those in USEPA (2010) by 100% or greater due to differences in the slope factors (up to 100% difference) as well as differences in life table analysis results (12–27%). Perhaps most problematic, the first step of the analysis did not determine significant exposure-response relationships between formaldehyde and LHP endpoints for the metric (cumulative exposure) needed in the estimation of an IUR. The resulting analysis, while it can be mechanically performed, provides no valid or useful insights on the risks of formaldehyde exposure. Regulatory dependence on these analyses may therefore lead to erroneous guidance, policies and laws.

These results highlight the necessity of clear and transparent reporting of both methods and data used in the estimation of unit risk values. Values provided by the IRIS program of USEPA are relied upon by other federal and state agencies in regulatory decision-making related to the development of standards and guidelines for environmental, consumer product and workplace exposure to chemicals. The inability to duplicate these types of values only escalates the scientific debate over the applicability of these standards and the scientific data necessary to support conclusions regarding acceptable levels of human exposure to chemicals.

Acknowledgements

This project was supported by funding provided by the Research Foundation for Health and Environmental Effects (Contract number R0072). RFHEE is a 501(c) (3) tax-exempt organization established by the American Chemistry Council (ACC). Established in 1995, RFHEE works to address uncertainties and answer questions on health and environmental issues related to the production and use of chemistry. RFHEE works with industry, public agencies, academia and other foundations on projects that will furnish crucial information, peer-reviewed scientific research, expert panels, and workshops that will provide information for public policy. RFHEE receives contributions from government, industry (companies and trade organizations), and other industry partners who share its commitment to improving the factual and scientific understanding about critical questions associated with and/or impacting chemistry. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of any manuscript. The funders were given the opportunity to review draft manuscripts at the time of external peer review. The purpose of such review was to allow input on the clarity of the science presented but not on interpretation of the research findings. The researchers' scientific conclusions and professional judgments were not subject to the funders' control.

Most of the authors (Gentry, Van Landingham, and Mundt) are employees of Ramboll Environ US Corporation, and performed this work as part of their normal employment. Ramboll Environ US Corporation is a consulting firm providing services in environmental and health sciences matters to private firms, trade organizations, and government agencies. Mr. Allen provided senior technical review on the manuscript and its content as an independent consultant with fee for service. The authors had sole responsibility for the analyses performed, the interpretations made, conclusions drawn and the writing of the paper, which may not necessarily reflect the views of RFHEE. None of the authors have appeared as experts in any litigation related to formaldehyde.

Appendix A.. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.yrtph.2016.10.011.

Transparency document

Transparency document related to this article can be found online at http://dx.doi.org/10.1016/j.yrtph.2016.10.011.

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Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 3/10/2016 7:57:31 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: main doc
Attachments: FormaldehydeTRdraft12215.docx

IRIS Toxicological Review of Formaldehyde: New Science Summary for LHP Cancers

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NOVEMBER 7, 2016

RAMBOLL ENVIRON

June 2, 2010, EPA announced the release of the Draft Toxicological Review of Formaldehyde-Inhalation Assessment

USEPA 2010 Draft Formaldehyde IRIS Assessment

LHP Conclusions:

- *Weight-of-evidence analysis* – causal relationships between formaldehyde exposure and all LHP cancers as a group, all leukemias as a group and all myeloid leukemias as a group
- *Epidemiologic evidence* – considered supportive of a causal association between formaldehyde exposure and both Hodgkin lymphoma and multiple myeloma
- *Mode of action* – dependent upon hematological and genetic results reported by Zhang et al. (2010); results need to be extended and repeated
- *Dose-response assessment* – Beane-Freeman et al. (2009) judged to have exposure-response data adequate for the derivation of unit risk estimates

NAS 2011 Provides recommendations on Draft IRIS assessment relevant to LHPs

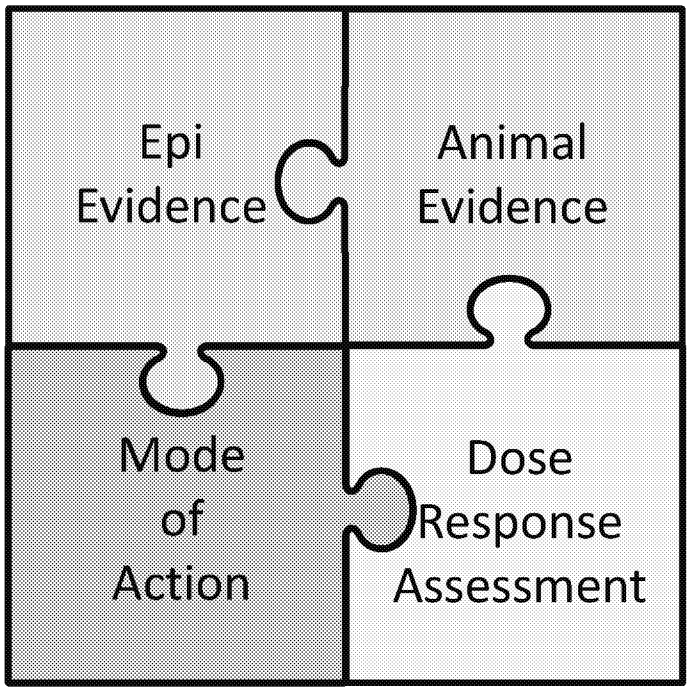
- **Animal Evidence**
  - Paucity of evidence for LHPs from animal models
- **Epidemiological Evidence**
  - Use specific diagnoses available
  - Re-evaluate peak vs. cumulative dose-metric
  - Define strengths, weaknesses, and inconsistencies of key studies
  - Justify use of Beane-Freeman et al. (2009)
- **Mode of Action**
  - Revisit arguments that support causality
  - Improve understanding of endogenous formaldehyde
  - Reconcile divergent statement regarding systemic delivery
  - data insufficient for cytogenetic effects at distant sites

NAS Recommendations relevant to LHPs (cont'd)

- **Quantitative Analyses**
  - Independent analysis needed
  - Alternative extrapolation models needed
  - BBDR modelling should be used
- **Evidence Integration**

  "EPA's approach to weight of evidence should include "a single integrative step after assessing all of the individual lines of evidence". Although a synthesis and summary are provided, the process that EPA used to weigh different lines of evidence and how that evidence was integrated into a final conclusion are not apparent in the draft assessment and should be made clear in the final version."

Integration of Evidence for LHPs



Lymphohematopoietic cancers - "…absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data, and the lack of mechanistic data."

New Animal Evidence
NAS Comment: Paucity of Evidence

- **Morgan et al. 2014**
  - No cases of leukemia or lymphohematopoietic neoplasia were seen. Formaldehyde inhalation did not cause leukemia in genetically predisposed C3B6.129F1-*Trp53*tm1Brd mice.
- **Morgan et al. 2015**
  - Formaldehyde inhalation did not cause leukemia or lymphohematopoietic neoplasia in genetically predisposed p53-Haploinsufficient mice.
- *Attempts to publish these results have been unsuccessful; however, in an October 17, 2016 response to a letter from ACC urging publication of these reports, Dr. Linda Birnbaum stated, "All things considered, an NTP Research Report seems like a good solution."*

New Epidemiological Evidence
NAS Recommendation: Use specific diagnoses

- Checkoway *et al.* (2015) received original study data from NCI, verified original results of Beane Freeman *et al.* 2009 and conducted additional analyses that separated myeloid leukemias into acute myeloid leukemias (AMLs) and chronic myeloid leukemias (CML).
- Associations seen between formaldehyde exposure and Hodgkin lymphoma and chronic myeloid leukemia (CML) have not been observed in other studies and are not considered plausible.
- No other LHP malignancy was associated with either chronic or peak exposure to formaldehyde.

No excess mortality from AML or CML observed

	Checkoway et al. 2015				Beane Freeman et al. 2009			
	Non-exposed (n=3,136)		Exposed (n=22,483)		Non-exposed (n=3,108)		Exposed (n=22,511)	
	Obs	**SMR (95% CI)**	**Obs**	**SMR (95% CI)**	**Obs**	**SMR (95% CI)**	**Obs**	**SMR (95% CI)**
Myeloid leukemia	4	**0.69** (0.19-1.76)	44*	**0.86** (0.64-1.16)	4	**0.65** (0.35–1.74)	44	**0.90** (0.67–1.21)
AML	4	**0.93** (0.25-2.37)	30	**0.80** (0.56-1.14)	NR		NR	
CML	0		13	0.97 (0.56-1.67)	NR		NR	

US mortality rates used as the reference

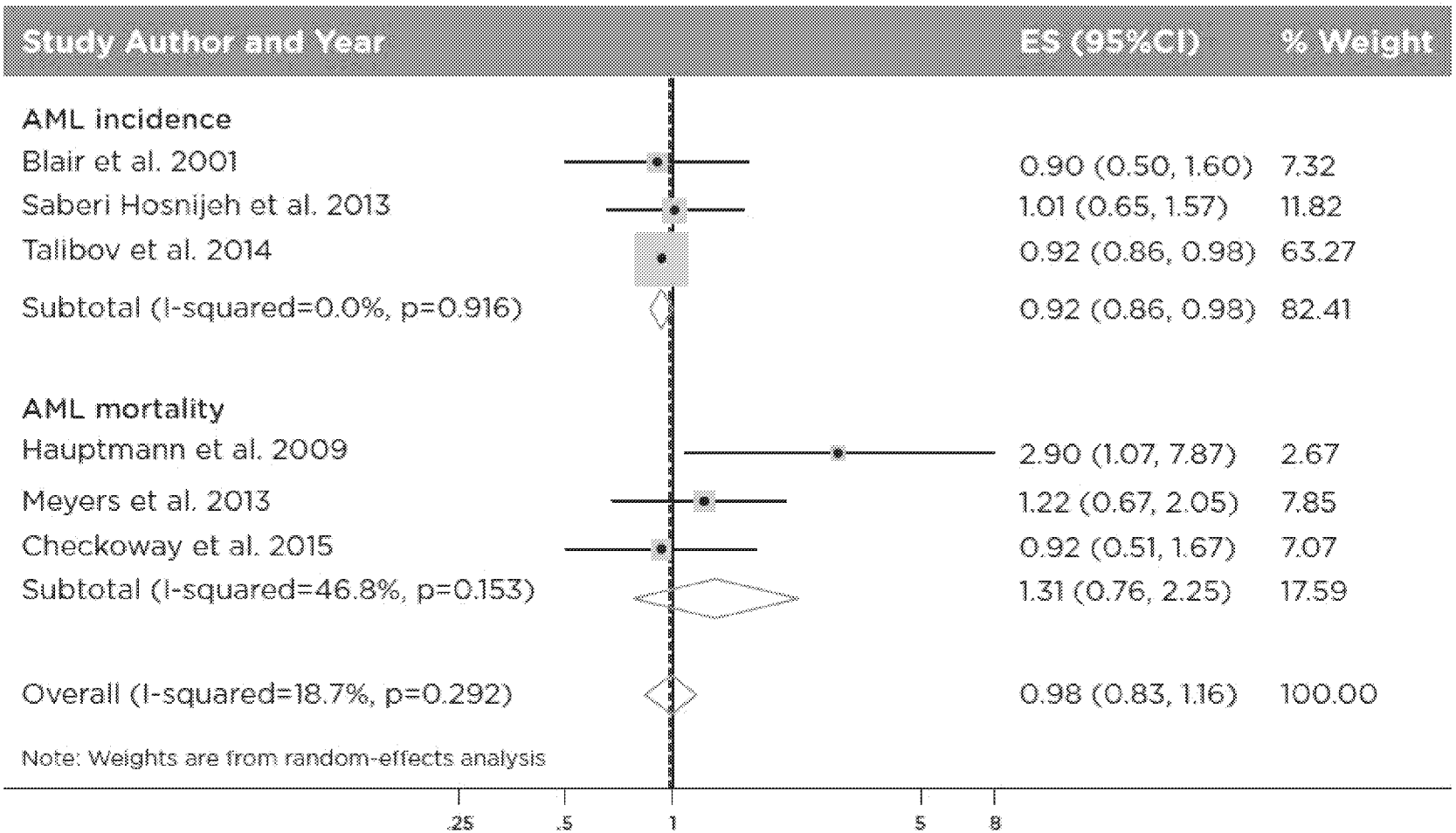
*One death was coded to ICD-8 205.9, unspecified myeloid leukemia.

Association between peak exposure and mortality from most specific diagnosis available (Checkoway et al. 2015)

	No peak		≥2.0 to < 4.0 ppm		≥4.0 ppm		
Diagnosis	Obs	HR (95% CI)	Obs	HR (95% CI)	Obs	HR (95% CI)	P trend
Hodgkin lymphoma	15	1.0 (referent)	5	2.18 (0.77-6.19)	7	3.38 (1.30-8.81)	0.01
Myeloid leukemia	27	1.0 (referent)	11	2.09 (1.03–4.26)	10	1.80 (0.85–3.79)	0.06
AML	**21**	**1.0 (referent)**	**7**	**1.71 (0.72–4.07)**	**6**	**1.43 (0.56–3.63)**	**0.31**
CML	**6**	**1.0 (referent)**	**3**	**2.62 (0.64–10.66)**	**4**	**3.07 (0.83–11.40)**	**0.07**

No increased risk of AML is seen in relation to occupational exposure to formaldehyde

AML studies stratified by incidence vs. mortality



New Epidemiological Evidence

NAS Comment: Re-evaluate peak vs. cumulative dose metric

- Checkoway *et al*. 2015 evaluated peak exposure and reported time since first and time since last peak exposure
  - Among the 13 of 34 AML deaths in the full cohort with peak exposures more than 2.0 ppm, only four worked in jobs with peaks within the 20 years preceding death
  - Only one AML death occurred (similar to expected) within the typical latency window of 2 to 15 years.

New Mode of Action Evidence

NAS Comment: Revisit arguments that support causality

- **Zhang et al. 2010**
  - reported significant changes* in blood parameters (WBC, lymphocyte, platelets, RBC counts) and increased frequency of aneuploidy in cultures of cells in vitro between exposed and unexposed workers.
- Conclusions:

  "…formaldehyde exposure can have an adverse effect on the hematopoietic system and that leukemia induction by formaldehyde is ***biologically plausible***, which heightens concerns about its leukemogenic potential from occupational and environmental exposures." (emphasis added)

*Actually, study was a cross-sectional design that reported differences in blood parameters between exposed workers and unexposed workers at one point in time. Changes in blood parameters over time were not investigated.

New Mode of Action Evidence

NAS Comment: Revisit arguments that support causality

- Gentry et al. (2013) re-analyzed data obtained via FOIA, **not including withheld individual exposure estimates**, suggesting other factors may have contributed to effects, which also may have arisen in vitro rather than in vivo.
  - significant methodological limitations identified (e.g., failure to follow study protocol) raised serious questions about whether this evidence provides support for a causal relationship between formaldehyde exposure and leukemia or lymphoid malignancies.

New Mode of Action Evidence

NAS Comment: Revisit arguments that support causality

- Mundt et al. (submitted) re-analyzed FOIA data **including individual exposure data** obtained via DTA from NCI
  - *Comparing exposed to unexposed* – Analyses indicated few relationships between effects reported and formaldehyde exposure. The direction of some differences was opposite of what would be expected if caused by a toxic exposure.
  - *Correlation among exposed* – no correlation with formaldehyde exposure was seen for any parameter; sex and smoking were predictive of several differences in the blood measures.
  - Evaluation of aneuploidies – No relationship between formaldehyde exposure and monosomy 7 or trisomy 8 were seen – even assuming protocol had been followed properly.

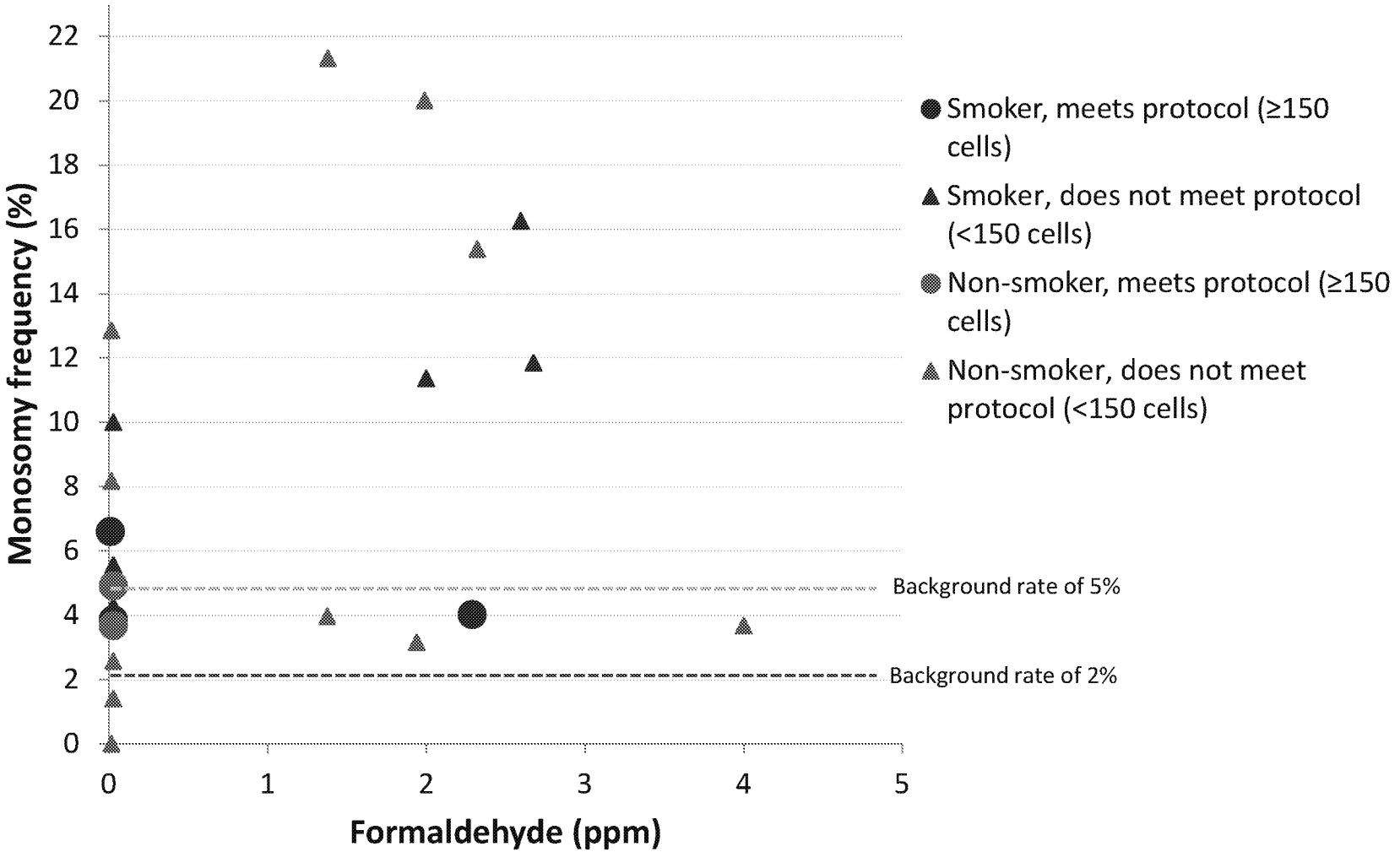
Association between formaldehyde exposure and WBC and RBC counts and components

Exposure	Blood Count Adjusted RR	95% CI	†p-value	Blood Count Adjusted RR	95% CI	†p-value
	WBC			**RBC**		
Unexposed	1.00			1.00		
<1.3 ppm	***0.87**	0.78-0.97		***0.94**	0.91-0.98	
≥1.3 ppm	***0.85**	0.76-0.96	0.943	***0.94**	0.90-0.98	0.947
	Lymphocytes			**Hemoglobin**		
Unexposed	1.00			1.00		
<1.3 ppm	***0.85**	0.75-0.96		0.98	0.94-1.01	
≥1.3 ppm	***0.79**	0.69-0.90	0.660	0.99	0.95-1.03	0.818
	Monocytes			**MCV**		
Unexposed	1.00			1.00		
<1.3 ppm	0.90	0.77-1.06		1.03	0.99-1.08	
≥1.3 ppm	0.89	0.75-1.04	0.973	1.06	1.02-1.11	0.550
	Granulocytes			**Platelets**		
Unexposed	1.00			1.00		
<1.3 ppm	0.87	0.75-1.01		***0.85**	0.75-0.96	
≥1.3 ppm	0.88	0.75-1.03	0.997	0.91	0.80-1.03	0.674

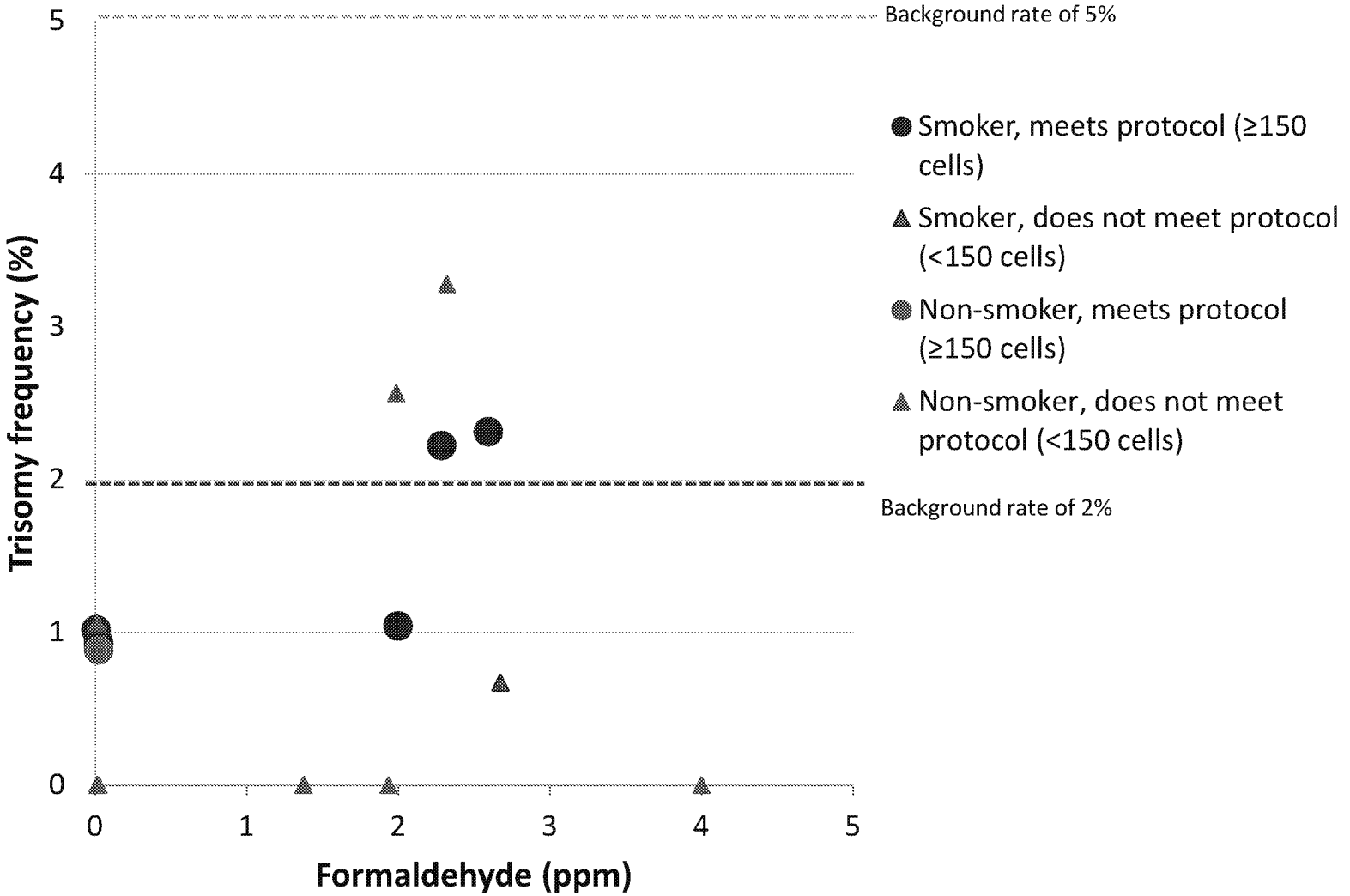
†Comparison between exposed categories

*p<0.05 compared with unexposed

Monosomy 7


Monosomy frequency (%)
22
20
18
16
14
12
10
8
6
4
2
0
0
1
2
3
4
5
Formaldehyde (ppm)
Smoker, meets protocol (≥150 cells)
Smoker, does not meet protocol (<150 cells)
Non-smoker, meets protocol (≥150 cells)
Non-smoker, does not meet protocol (<150 cells)
Background rate of 5%
Background rate of 2%

Trisomy 8


Trisomy frequency (%)
5
4
3
2
1
0
0
1
2
3
4
5
Formaldehyde (ppm)
Background rate of 5%
Background rate of 2%
Smoker, meets protocol (≥150 cells)
Smoker, does not meet protocol (<150 cells)
Non-smoker, meets protocol (≥150 cells)
Non-smoker, does not meet protocol (<150 cells)

Dose-Response Assessment
NAS Recommendation: Independent Analyses

- **Van Landingham et al. (2016)**
  - Using the original data from the key study (Beane Freeman et al. 2009), focused on duplication of the draft inhalation unit risk (IUR) and addressed comments from NAS regarding inputs and assumptions
- ***Conclusions***
  - *"Overall, documentation of the methods lacked sufficient detail to allow for replication of the unit risk estimates, specifically for Hodgkin lymphoma and leukemias, the key systemic endpoints selected by IRIS. The lack of apparent exposure-response relationships for selected endpoints, raises the question whether quantitative analyses are appropriate for these endpoints, and if so, how results are to be interpreted."*

Comparison of modelling statistics from Van Landingham et al. 2016 to statistics reported in USEPA (2010)

	Cox Regression	Logistic Regression			Poisson Regression		USEPA (2010)
	p-value [a]	R^2	LR p-value[b]	p-value [a]	LR p-value[b]	p-value [a]	p-value
Hodgkin lymphoma (201)	0.013	0.0133	0.098	0.019	0.09	0.037	0.06
Leukemia (204 – 207)	0.058	0.0017	0.35	0.055	0.003	<0.001	0.08
Leukemia (204 – 207, excluding 204.1)	0.239	0.0011	0.64	0.206	0.034	0.013	---
Acute myeloid leukemia (205.0)	0.844	0.0016	0.82	0.869	0.81	0.80	---

[a] p-values reflect the precision of any association between exposure and response, and show the probability that the beta value is not significantly different from zero. P-values < 0.05 indicate that the beta parameter is significantly different from zero.

[b] The likelihood ratio p-values of difference between a null and dose-dependent model (e.g. test of β=0) where small p-values reject the hypothesis that β=0. ..

Relative risk for Hodgkin lymphoma based on peak exposure from Poisson model stratified by calendar year, age, sex, and race and adjusted for pay category

				Van Landingham et al. 2016		Beane Freeman et al. 2009	
	Subjects	Person-years	Deaths	RR	CI	RR	CI
0	3,139	104,386	2	**3.32**	0.60-18.26	**0.67**	0.12-3.60
0 to 2	10,302	415,987	6	**1.0**	Referent	**1.0**	Referent
2 to 4	6,010	254,723	8	**0.76**	0.30-1.89	**3.30**	1.04-10.50
≥4 ppm	6,198	256,618	11	**2.96**	0.94-9.27	**3.96**	1.31-12.02

p trend[1] (reported by Beane Freeman)		0.01
p trend[2] (reported by Beane Freeman)		0.004
log likelihood (reported by Van Landingham)	-309.87	
p-value[3] (reported by Van Landingham)	0.04	

[1]Two-sided likelihood ratio test (1 df) of zero slope for continuous formaldehyde exposure among exposed person-years only.

[2] Two-sided likelihood ratio test (1 df) of zero slope for continuous formaldehyde exposure among unexposed and exposed person-years.

[3] Two-sided likelihood ratio test

Relative risk for all leukemias based on peak exposure from Poisson model stratified by calendar year, age, sex, and race and adjusted for pay category

				Van Landingham et al. 2016		Beane Freeman et al. 2009	
	Subjects	Person-years	Deaths	RR	CI	RR	CI
0	3,139	104,386	2	**1.83**	0.76-4.40	**0.59**	0.25-1.36
0 to 2	10,302	415,987	6	**1.0**	Referent	**1.0**	Referent
2 to 4	6,010	254,723	8	**0.58**	0.36-0.93	**0.98**	0.60-1.62
≥4 ppm	6,198	256,618	11	**1.07**	0.66-1.75	**1.42**	0.92-2.18

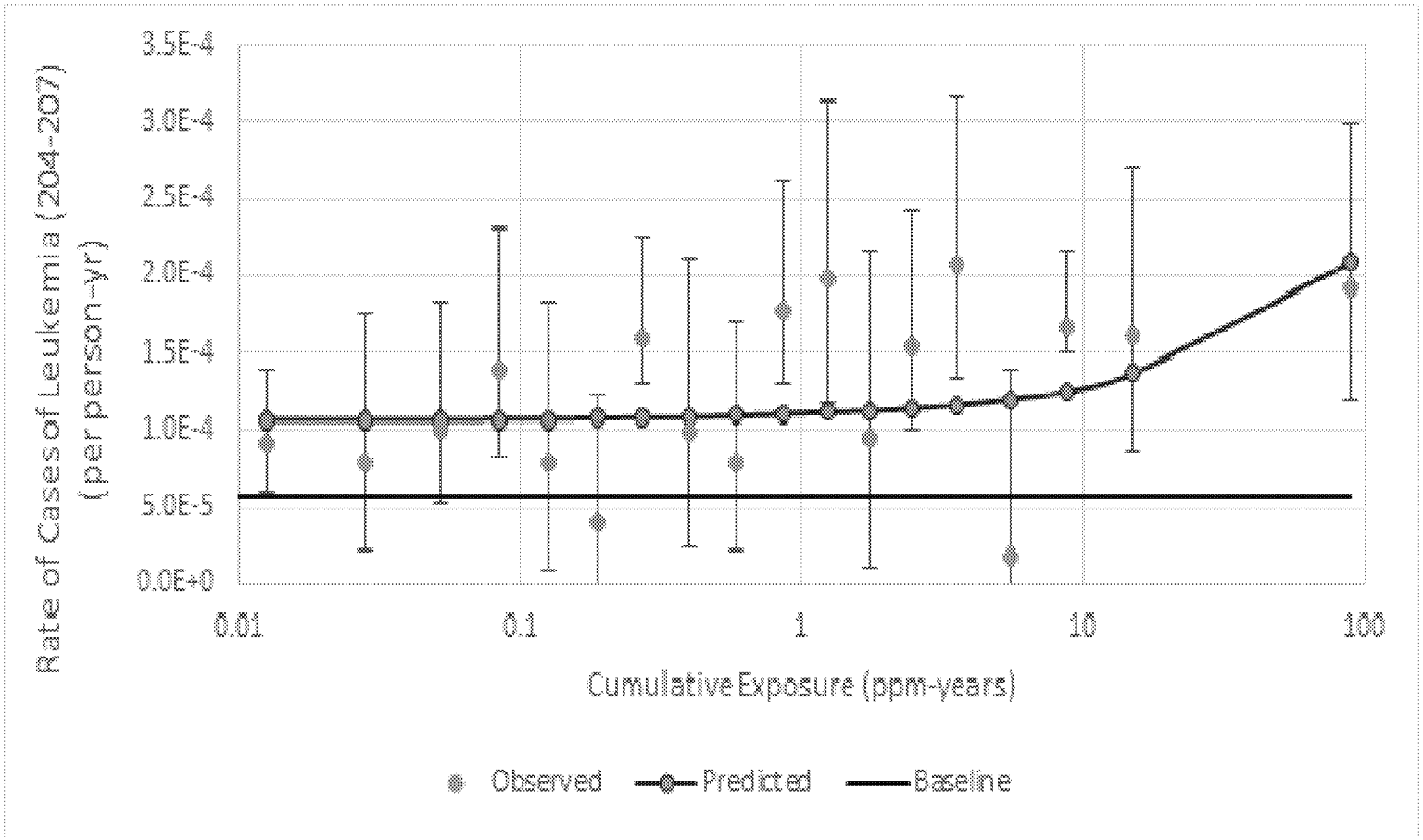
p trend[1] (reported by Beane Freeman)		0.12
p trend[2] (reported by Beane Freeman)		0.02
log likelihood (reported by Van Landingham)	-1177.94	
p-value[3] (reported by Van Landingham)	0.004	

[1]Two-sided likelihood ratio test (1 df) of zero slope for continuous formaldehyde exposure among exposed person-years only.

[2] Two-sided likelihood ratio test (1 df) of zero slope for continuous formaldehyde exposure among unexposed and exposed person-years.

[3] p-value for the likelihood ratio chi square test

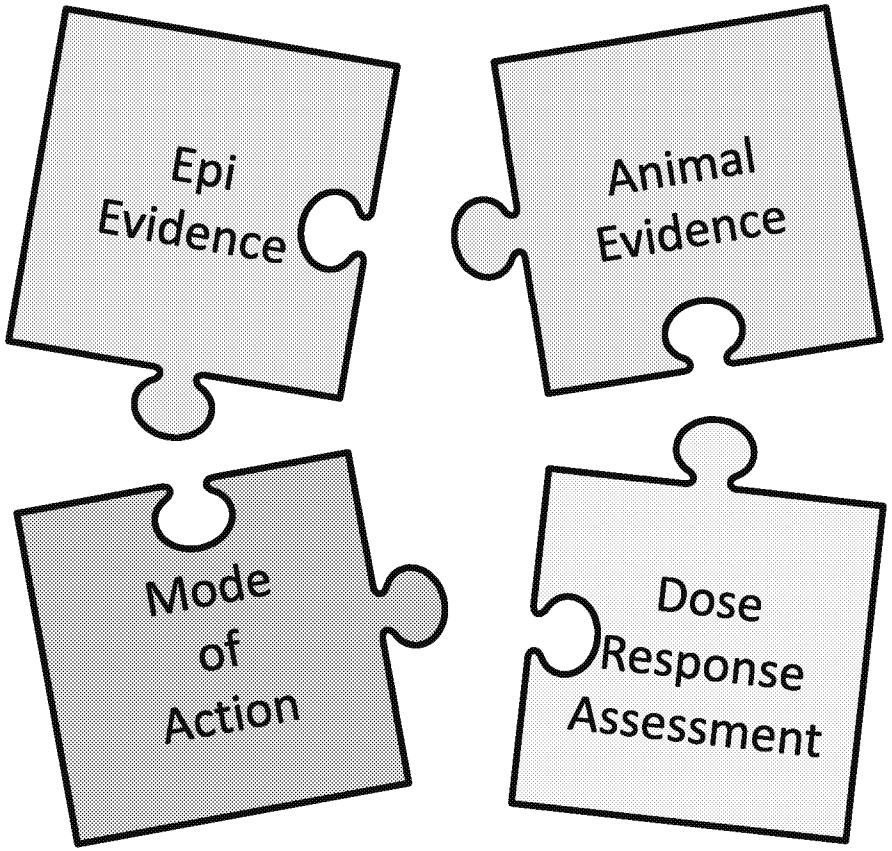
Comparison of Estimated Cases from the Poisson Regression model to number of cases of Leukemias Observed at the end of follow-up period in the Beane Freeman et al. (2009) study. Observed and Predicted Results Over Full Observed Exposure Range



Dose-Response Assessment
NAS Recommendation: Independent Analyses

- **Van Landingham et al. 2016**
  - Large variability in the low dose region which is poorly fit by models
  - Unable to reproduce the Beta values reported in USEPA (2010)
  - Inconsistencies between life table instructions in USEPA (2010) and life table results reported

NAS 2011 Comments/Data Gaps



Addressing the NAS Comments provides increasing evidence of a lack of a causal association between formaldehyde exposure and lymphohematopoietic cancers

New Animal Evidence

NAS Recommendation	Addressed by
Data gap: Paucity of evidence for LHP from animal models	**Morgan et al. (2015)** • No cases of leukemia or lymphohematopoietic neoplasia were seen. Formaldehyde inhalation did not cause leukemia in genetically predisposed C3B6.129F1-Trp53tm1Brd mice. **Morgan et al. (2014)** • Formaldehyde inhalation did not cause leukemia or lymphohematopoietic neoplasia in genetically predisposed p53-Haploinsufficient mice.

New Epidemiological Evidence

NAS Recommendation	Addressed by
Define strengths, weaknesses, and inconsistencies of key studies	**Checkoway et al. 2012** • A critical review of the epidemiological literature indicated no consistent or strong epidemiologic evidence that formaldehyde is causally related to any lymphohematopoetic malignancies. The absence of established toxicological mechanisms further weakens any arguments for causation.
Use specific diagnoses available	**Checkoway et al. 2015** • New analyses of the NCI formaldehyde workers cohort specifically for AML are reported. Results do not support the hypothesis that formaldehyde causes AML. • Associations seen between formaldehyde exposure and Hodgkin leukemia and chronic myeloid leukemia (CML) have not been observed in other studies and are not considered plausible. **Boffetta et al. 2016** • Some prominent recent evaluations have concluded that formaldehyde is leukemogenic, especially for the myeloid types1,12. • However, overall evidence from studies specifically examining occupational exposure to formaldehyde and AML demonstrates no clear or consistent increased risk of AML. The meta-RR estimates are not statistically significantly elevated, and the null findings were tolerant to various sensitivity tests, including omitting the most influential study. • Given the lack of animal studies demonstrating leukemogenicity, a lack of direct evidence for a mode of action and compelling new experimental evidence that formaldehyde is incapable of reaching bone marrow13, the absence of any clearly or convincingly increased meta-RR adds to the growing body of evidence indicating that formaldehyde exposure is unlikely to cause AML.

New Epidemiological Evidence

NAS Recommendation	Addressed by
Re-evaluate peak vs. cumulative dose-metric	**Checkoway et al. 2015** • Acute myeloid leukemia (AML) was unrelated to cumulative, average or peak exposure. • Few deaths occurred within 20+ years of last peak exposure. • Hodgkin lymphoma relative risk estimates suggested trends for both cumulative (Ptrend= 0.05) and peak (Ptrend = 0.003) exposures. • Suggestive associations with peak exposure observed for chronic myeloid leukemia, based on very small numbers. • No other lymphohematopoietic malignancy was associated with either chronic or peak exposure.
Justify use of Beane-Freeman et al	**Meyers et al. 2013** • Extended follow-up of 11,098 employees of three garment manufacturing facilities. Results demonstrated limited evidence for formaldehyde exposure and any LHM including AML, based on 14 observed cases. **Coggon et al. 2014** • Extended follow-up of a cohort of 14,008 chemical workers at 6 factories in England and Wales, covering the period 1941-2012. Results provide no support for an increased hazard of myeloid leukemia from formaldehyde exposure.

New Mode of Action Evidence (1)

NAS Recommendation	Addressed by
Data gap: Improve understanding of endogenous formaldehyde	**Schroeter et al. 2014** • Endogenous formaldehyde in nasal tissues did not significantly affect flux or nasal uptake predictions at exposure concentrations > 500 ppb; however, reduced nasal uptake was predicted at lower exposure concentrations. **Yu et al. 2015** • With the application of highly sensitive instruments and accurate assays, inhaled formaldehyde was found to reach nasal respiratory epithelium, but not other tissues distant to the site of initial contact. In contrast, endogenous adducts were readily detected in all tissues examined with remarkably higher amounts present. Moreover, the amounts of exogenous formaldehyde-induced adducts were 3- to 8-fold and 5- to 11-fold lower than the average amounts of endogenous formaldehyde-induced adducts in rat and monkey nasal respiratory epithelium, respectively.
Reconcile divergent statement regarding systemic delivery	**Yu et al 2015; Edrissi et al. 2013; Moeller et al. 2011; Lu et al. 2011** • Based on a sensitive analytical method that can measure endogenous versus exogenous formaldehyde DNA adducts, the multiple studies demonstrated that inhaled exogenous formaldehyde only reached rat or monkey noses, but not tissues distant to the site of initial contact.

New Mode of Action Evidence (2)

NAS Recommendation	Addressed by
Revisit arguments that support causality	**Gentry et al. 2013** • Reanalysis of selected raw data from the Zhang et al. (2010) study do not support a causal association between formaldehyde and myeloid leukemia or lymphoid malignancies. Because of the significant methodological limitations, unless the results can be confirmed using appropriate methodologies designed to detect in vivo events, the reanalysis of the results provided by Zhang et al. (2010) raise sufficient questions that limit the use of Zhang et al. (2010) to support the hypothesis that formaldehyde exposure is causally related to leukemia or lymphoid malignancies. **Mundt et al. 2016 (submitted for publication)** • Reanalysis of raw data from Zhang et al. (2010) including exposure data. Results showed that differences in white blood cell, granulocyte, platelet, and red blood cell counts are not exposure-dependent. Among formaldehyde-exposed workers, no association was observed between individual average formaldehyde exposure estimates and frequency of aneuploidy, suggested by the original study authors to be indicators of myeloid leukemia risk.

New Mode of Action Evidence (3)

NAS Recommendation	Addressed by
Data gap: data insufficient for cytogenetic effects at distant sites	**Albertini et al. 2016** • Critical review of the genotoxicity literature found no convincing evidence that exogenous exposures to FA alone, and by inhalation, induce mutations at sites distant from the portal of entry tissue as a direct DNA reactive mutagenic effect – specifically not in the bone marrow. • Review of the existing studies of hematotoxicity, likewise, failed to demonstrate myelotoxicity in any species– a probable prerequisite for leukemogenesis.

New Dose-Response Assessments (1)

NAS Recommendation	Addressed by
Independent analysis needed	**Van Landingham et al. 2016** • The documentation of the methods applied in the USEPA (2010) IRIS document lacks sufficient detail for duplication of the unit risk estimates provided, even with the availability of the raw data from the Beane Freeman et al. (2010). This lack of transparency and detail may result in different estimates of unit risks, especially as initial analyses resulted in a lack of a significant dose-response relationship for selected endpoints.
Alternative extrapolation models needed	**Starr and Swenberg 2013** • Results of the "Bottom-up " approach indicate that recent top-down risk extrapolations from occupational cohort mortality data for workers exposed to formaldehyde are overly conservative by substantial margins. **Starr and Swenberg 2016** • Updated "Bottom-Up" risk estimates heighten the marked contrasts that are present between the previous estimates and the corresponding USEPA estimates, with the larger difference for leukemia being due primarily to the significantly improved detection limit for the analytical method used in quantitating DNA adduct numbers.

New Dose-Response Assessments (2)

NAS Recommendation	Addressed by
BBDR modelling should be used	**Clewell H, et al. (in preparation)** • Expansion of the model to incorporate recent data on endogenous levels of formaldehyde is in development. This will incorporate the most recent science to better understand when exogenous formaldehyde exposure appreciably alters normal endogenous formaldehyde concentrations. **Gentry PR, et al. (in preparation)** • Review of the utility of BBDR modeling for use in risk assessment focusing primarily on the use of BBDR modeling in predicting the human health risk of formaldehyde exposure. This review addresses the current published criticisms for BBDR modeling use in risk assessment, and highlights the advantages of expanding the application of BBDR modeling in risk assessment.

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Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 10/19/2016 5:31:01 PM
To: Birchfield, Norman [Birchfield.Norman@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]
CC: Bussard, David [Bussard.David@epa.gov]
Subject: RE: 1st draft briefing sheet for Kavlock
Attachments: HCHOBriefKavlock042816.pptx; Kavlock_Apr2016_bckgrnd.docx; Kavlockoutline041916.pptx

Hi Norm,
Thanks. There are the materials we did last time which was a more formal briefing than I understand that this one will be.
-Barbara

From: Birchfield, Norman
Sent: Wednesday, October 19, 2016 1:16 PM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>
Subject: 1st draft briefing sheet for Kavlock

Hi Barbara and Andrew – I've made an attempt at a briefing sheet for Kavlock. Please edit as you see appropriate. I think we can discuss the sheet and the briefing at our meeting with David on Monday. We'll need to send this to the IOAA on Tuesday. Thanks

Norman Birchfield, Ph.D. / National Center for Environmental Assessment / U.S. Environmental Protection Agency / phone: (703) 347-0174

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 5/9/2018 3:36:21 PM
To: Lidka Maslankiewicz [lidka.maslankiewicz@rivm.nl]; Kraft, Andrew [Kraft.Andrew@epa.gov]
CC: Paul Janssen [paul.janssen@rivm.nl]; Theo Vermeire [theo.vermeire@rivm.nl]
Subject: RE: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))

Dear Lidka,
Thank you very much for this information. We also found our discussion helpful and we will contact you when we can provide an update.
Regards, Barbara

From: Lidka Maslankiewicz [mailto:lidka.maslankiewicz@rivm.nl]
Sent: Wednesday, May 09, 2018 11:04 AM
To: Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: Paul Janssen <paul.janssen@rivm.nl>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))

Dear Barbara and Andrew,

Thank you very much for the interesting discussion; we are already looking forward to the next one!

As promised, we send you the NL draft document on the limit value for formaldehyde (Paul is currently working on this):

Here is link to all documents from REACH Harmonized Classification and Labelling (CLP) process:
https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180a13be9

Here are two documents from CLP (link above), which might be the most interesting for you:

Here is the link to the public documents for REACH Substance Evaluation process. The deadline for the Conclusion Documents on the general public indoor exposure and worker exposure is October 2018.

https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e6413

Kind regards

Lidka

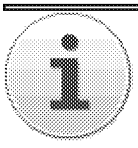
Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
Antonie van Leeuwenhoeklaan 9 | 3721 MA Bilthoven
Postbus 1 | 3720 BA Bilthoven
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 5/9/2018 1:02:05 PM
To: Lidka Maslankiewicz/RIVM/NL [lidka.maslankiewicz@rivm.nl]
Subject: RE: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))

Hi Lidka,
The number you gave we are getting a message that it is not in service. Did you give me all the numbers I need to dial an international callk?

-----Original Appointment-----
From: Lidka Maslankiewicz/RIVM/NL [mailto:lidka.maslankiewicz@rivm.nl]
Sent: Monday, April 09, 2018 8:30 AM
To: Lidka Maslankiewicz/RIVM/NL; Glenn, Barbara; Kraft, Andrew; Paul Janssen/RIVM/NL; Theo Vermeire/RIVM/NL
Subject: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))
When: Wednesday, May 09, 2018 3:00 PM-4:30 PM W. Europe.
Where:



Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))

05/09/2018 -

No Location Information

Lidka Maslankiewicz has sent updated information; description has changed

Required: glenn.barbara@epa.gov, Kraft.Andrew@epa.gov, Paul Janssen/RIVM/NL@RIVM, Theo Vermeire/RIVM/NL@RIVM

Description

Agenda:

1. Round of mutual introduction

2. Presentation of US EPA and NL ongoing activities on formaldehyde risk assessment.

3. NL questions on 2010 draft IRIS toxicological review on formaldehyde:

- Are there any new developments in the process at EPA of evaluating formaldehyde?

- Would it be possible for us to use the data and concept, with agreed referencing?

- Do you plan any additional modelling to be done for deriving the unit risks from the NCI-cohort data, according to the advice from National Research Council?

- Do you plan to derive unit risk derived from animal data?

4. AOB

Please, call:

+31 30 274 3160

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 4/9/2018 12:01:46 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Lidka Maslankiewicz [lidka.maslankiewicz@rivm.nl]
CC: Theo Vermeire [theo.vermeire@rivm.nl]; Paul Janssen [paul.janssen@rivm.nl]; Joke Herremans [joke.herremans@rivm.nl]; Els Smit [els.smit@rivm.nl]
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hello,
I'm available on the 10th and possibly April 19th. May 10th may be best because there may be others interested from here.
Thanks for getting in touch with us.
Regards, Barbara

From: Kraft, Andrew
Sent: Monday, April 09, 2018 7:53 AM
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>
Cc: Theo Vermeire <theo.vermeire@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Joke Herremans <joke.herremans@rivm.nl>; Els Smit <els.smit@rivm.nl>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Good to hear from you. We are still interested in having a discussion.

Of the times you proposed, the only one I currently have available is May 10th. If that does not work for someone else, I can probably move something to make April 19th work. The other 2 times are probably not possible.

I look forward to our discussion.

-Andrew

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Monday, April 9, 2018 4:50 AM
To: Glenn, Barbara; Kraft, Andrew
Cc: Theo Vermeire; Paul Janssen; Joke Herremans; Els Smit
Subject: Fw: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Barbara and Andrew,

Please, let us know if you are still interested in the discussion on formaldehyde assessment. The topics mentioned in our previous mail are still of interest for us.

We would like to propose the following dates and times for a telephone conference:

12th and 19th of April 2018, 9 – 10 am EST (15:00 – 16:00 our time), or

2nd and 10th of May 2018, 9 – 10 am EST (15:00 – 16:00 our time).

If you prefer different dates or times, please, let us know.

We hope to hear from you soon.

Kind regards

Lidka

Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
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Postbus 1 | 3720 BA Bilthoven
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl
----- Forwarded by Lidka Maslankiewicz/RIVM/NL on 04/09/2018 10:48 AM -----

From: Lidka Maslankiewicz/RIVM/NL
To: "Glenn, Barbara" <Glenn.Barbara@epa.gov>,
Cc: "Bussard, David" <Bussard.David@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, Els Smit <els.smit@rivm.nl>, Joke Herremans <joke.herremans@rivm.nl>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>, Paul Janssen <paul.janssen@rivm.nl>, "Thayer, Kris" <thayer.kris@epa.gov>, Theo Vermeire <theo.vermeire@rivm.nl>
Date: 11/22/2017 04:32 PM
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Barbara and Andrew,

It is our turn to apologize for a delay.

Yes, we would be very interested to talk about the formaldehyde assessment and its methods for quantification of cancer risk for NPC. As I have already informed you, we are currently in the process of updating our national air limit for this chemical and we would like to use the data as presented in the 2010 draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data as presented in this Draft.

We would appreciate the opportunity to discuss the current status of the IRIS Toxicological Review of Formaldehyde.

We are also interested if there is any possibility to use the data (especially derived inhalation cancer unit risk for NPC (Nasopharyngeal Cancer)), without referring as to an official EPA position, but rather a scientific approach.

We have noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

April 30th to May 1st, 2014 Crystal City Marriott at ...

www.epa.gov

Luoping Zhang, University of California at Berkeley, discussant Robert Snyder, Rutgers University (retired), discussant Martha Sandy, California EPA , discussant

We also would like to know, how will US-EPA react to the comments of NAS (especially their comments on the calculation of the unit risks)? Moreover, will the unit risk calculation change in the near future?

Here are several dates we would like to propose:

13th, 20th, 21st or 22nd of December 2017, 9 – 10 am EST (15:00 – 16:00 our time), or

17th, 18th, 24th or 25th of January 2018, 9 – 10 am EST (15:00 – 16:00 our time).

We hope to hear from you soon.

Kind regards

Lidka

Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

From: "Glenn, Barbara" <Glenn.Barbara@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>,
Cc: "Bussard, David" <Bussard.David@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, Els Smit <els.smit@rivm.nl>, Joke Herremans <joke.herremans@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Thayer, Kris" <thayer.kris@epa.gov>, Theo Vermeire <theo.vermeire@rivm.nl>
Date: 10/10/2017 04:48 PM
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Lidka,
We would like to schedule a time to talk about the formaldehyde assessment and its methods for quantification of cancer risk for

NPC. It would be great to explore what might be possible. I have some proposed dates and times for you to select from. Will this be possible for you?

Oct. 30 9 – 10 am EST
Nov 1 9 – 10 am EST
Nov 7 9 – 10 am EST

Thank you very much for your patience with our process and timing. Regards, Barbara and Andrew

From: Lidka Maslankiewicz [mailto:lidka.maslankiewicz@rivm.nl]
Sent: Friday, September 22, 2017 4:54 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Els Smit <els.smit@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Joke Herremans <joke.herremans@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Thayer, Kris <thayer.kris@epa.gov>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Andrew and Barbara

Thank you for your reply, apologies for not answering sooner.

The issue is that we would like to use the data as presented in the 2010 Draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data.

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer? Something in line with: *"It should be noted that the methodology used for the quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."*

We also noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

Maybe we can first do the exchange via mail and decide later on if a telephone conference is useful.

Kind regards

Lidka

Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

From: "Kraft, Andrew" <Kraft.Andrew@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>,
Cc: Els Smit <els.smit@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Joke Herremans" <joke.herremans@rivm.nl>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Bussard, David" <Bussard.David@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>

Date: 09/08/2017 05:21 PM
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment . We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations,
Andrew and Barbara

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Tuesday, August 29, 2017 7:59 AM
To: Kraft, Andrew
Cc: Els Smit; Paul Janssen; Joke Herremans
Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

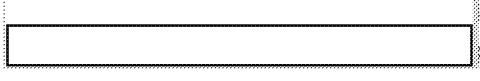
Dear Dr Kraft,
My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.
We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response" (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ...
cfpub.epa.gov
EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ...

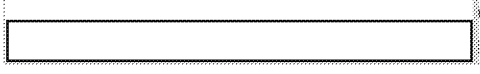
Kind regards
Lidka
Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products

tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

	RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het informatiecentrum ...

	Rijksinstituut voor Volksgezondheid en Milieu - RIVM www.rivm.nl Dutch experts on climate change adaptation join forces. Fourteen Dutch knowledge institutes have joined forces to provide practical, demand-driven policy advice based ...

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
www.rivm.nl *De zorg voor morgen* begint vandaag

	RIVM www.rivm.nl Dit Nederlandse overheidsinstituut verzorgt informatie, monitoring en wetenschappelijke onderbouwing van het volksgezondheidsbeleid. Ook valt het informatiecentrum ...

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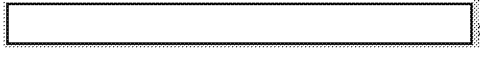
www.rivm.nl/en Committed to *health and sustainability*

	Rijksinstituut voor Volksgezondheid en Milieu - RIVM www.rivm.nl Dutch experts on climate change adaptation join forces. Fourteen Dutch knowledge institutes have joined forces to provide practical, demand-driven policy advice based ...

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www.rivm.nl *De zorg voor morgen* begint vandaag

Message

From: Glenn, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A2DC9210D2D4D02A623B33F87F49436-GLENN, BARBARA]
Sent: 6/9/2016 6:17:33 PM
To: Radke-Farabaugh, Elizabeth [radke-farabaugh.elizabeth@epa.gov]
Subject: formaldehyde assessment
Attachments: FormaldehydeTRdraft050616.docx

Message

From: Soto, Vicki [Soto.Vicki@epa.gov]
Sent: 6/28/2018 8:24:46 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: Fwd: Formaldehyde Overview document - first 50 pages
Attachments: formaldehyde_assessment overview_techedit_28Jun2018(50_Pages).docx; ATT00001.htm

I will look tomorrow. Please send comments to me.
Thanks!
Vicki

Sent from my iPhone

Begin forwarded message:

> **From:** "Carter, Greg" <Greg.Carter@icf.com>
> **To:** "Soto, Vicki" <Soto.Vicki@epa.gov>
> **Cc:** "Samuels, Crystal" <Samuels.Crystal@epa.gov>, "Kellar, Penelope" <Penelope.Kellar@icf.com>
> **Subject: Formaldehyde Overview document - first 50 pages**
>
> Hi Vicki,
> Here are the first 50 pages as requested. We will wait to hear from you before proceeding further.
>
> Thanks
>
> Greg

Message

From: Kraft, Andrew [Kraft.Andrew@epa.gov]
Sent: 2/21/2017 8:53:43 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]
Subject: FW:
Attachments: image2017-02-21-140137.pdf; ATT00001.htm

From: Shams, Dahnish
Sent: Tuesday, February 21, 2017 2:08 PM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: Fwd:

FYI -

Integrated Risk Information System (IRIS) Program
National Center for Environmental Assessment
Office of Research and Development, U.S. EPA
O: (703) 347-0167

Begin forwarded message:

> **From:** "VA-PYS-11251-M@epa.gov" <VA-PYS-11251-M@epa.gov>
> **To:** "Shams, Dahnish" <Shams.Dahnish@epa.gov>

Summary of National Academy of Sciences (NAS) Recommendations on Draft Formaldehyde IRIS Assessment and Notable Science Addressing the NAS Recommendations

Background

In 2010, the EPA's Integrated Risk Information System (IRIS) program released a draft assessment of formaldehyde and in 2011 the NAS completed its review of the EPA's draft IRIS assessment.[1] The NAS made recommendations for improving the evaluation of carcinogenicity, toxicity and dose-response modeling in the IRIS assessment. The American Chemistry Council Formaldehyde Panel has been committed to generating new science that directly addresses the specific recommendations made by the NAS. Over the past several years there has been a wealth of new data, both supported by the Panel and generated by other scientific experts, to inform the draft formaldehyde IRIS assessment. The below summary provides a brief overview of some of the available scientific evidence. These studies help fill data gaps, clarify interpretive ambiguities, and provide epidemiological, toxicological and mechanistic evidence to inform the formaldehyde science and address the NAS recommendations.

Epidemiological Evidence

The NAS report recommended reviewing determinations of causality for specific lymphohematopoietic (LHP) cancers, and reviewing the criteria that were used to weigh evidence and assess causality. In addition, because the draft IRIS assessment relies heavily on epidemiologic studies to determine causality, further discussion of the specific strengths, weaknesses, and inconsistencies in several key studies is needed. Evaluation of the most specific diagnoses available in the epidemiologic data (i.e., acute myeloblastic leukemia, chronic lymphocytic leukemia, and other specific lymphomas) is also needed, as well as clarification of the basis of EPA's interpretations of the results regarding the various dose metrics (peak versus cumulative) and the various LHP cancers. Additionally, the NAS also recommended resolving the conflicting statements in the IRIS assessment concerning which upper respiratory cancer sites were found to be causally associated with formaldehyde exposure. Below are several studies that focus on these areas.

- **Mundt K, Gallagher A, Dell L, et al. Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? (2017, submitted 10/28/16 and under review).** Conducted additional and refined analysis on the key underlying data (including specifically exposure information which had not been previously provided) utilized in a study relied upon in the draft IRIS assessment (e.g. Zhang et al. 2010). The analysis evaluates exposed and unexposed populations and any potential correlations between formaldehyde exposure and aneuploidy among the exposed populations. Results showed that differences in white blood cell, granulocyte, platelet, and red blood cell counts were not exposure-dependent. Additionally, among formaldehyde-exposed workers, no association was observed between individual formaldehyde exposure estimates and frequency of aneuploidy, which the original study authors suggested were indicators of myeloid leukemia risk. *Work Supported by the ACC Formaldehyde Panel members.

- **Marsh, G., Morfeld, P., Zimmerman, S., Liu, Y., and Balmert, L. (2016). An updated re-analysis of the mortality risk from nasopharyngeal cancer in the National Cancer Institute formaldehyde worker cohort study." Journal of Occupational Medicine and Toxicology 11, no. 1: 1.** The reanalysis provided little or no evidence to support NCI's suggestion of a persistent association between formaldehyde exposure and mortality from nasopharyngeal cancer. Specifically, the findings led to: (1) reduced standardized mortality ratios and relative risks in the remaining nine study plants in unaffected exposure categories, (2) attenuated exposure-response relations for formaldehyde and nasopharyngeal cancer for all the formaldehyde metrics considered

[1] NAS 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. National Research Council. ISBN: 0-309-21194-8, 194 pages. Available at: http://www.nap.edu/catalog/13142.html.

and (3) strengthened and expanded evidence that the earlier NCI internal analyses were non-robust and mis-specified as they did not account for a statistically significant interaction structure between plant group (Plant 1 vs. Plants 2-10) and formaldehyde exposure. *Work supported by the ACC Formaldehyde Panel members.

- **Checkoway, H., Dell, L.D., Boffetta, P., Gallagher, A.E., Crawford, L., Lees, P.S., and Mundt, K.A. (2015). Formaldehyde exposure and mortality risks from acute myeloid leukemia and other Lymphohematopoietic Malignancies in the US National Cancer Institute cohort study of workers in Formaldehyde Industries. Journal of Occupational and Environmental Medicine, 57(7), 785-794.** Authors obtained the data from the NCI cohort study via a Technology Transfer Agreement to replicate the findings reported by Beane Freemen et al. (2009) and to conduct additional analysis of associations of specific leukemias and lymphomas, especially acute myeloid leukemia, with formaldehyde exposure. Analyses were conducted including peak exposure as defined by Beane Freeman et al. (2009), as well as using an alternative more standard definition of peak exposure. The findings from this re-analysis fail to support the hypothesis that formaldehyde causes acute myeloid leukemia. Specifically, the results indicated: Acute myeloid leukemia was unrelated to "peak" or any other formaldehyde metric including the conventional cumulative exposure (also as reported in Beane Freeman (2009)). In fact, very few cohort members had any peak exposure within 20 years of death due to AML. There were suggestive associations with peak exposure only for chronic myeloid leukemia, albeit based on very small numbers. No other lymphohematopoietic malignancy was associated with either cumulative or peak exposure. *Work supported by the ACC Formaldehyde Panel members.

- **Coggon, D., Ntani, G., Harris, E. C., & Palmer, K. T. (2014). Upper airway cancer, myeloid leukemia, and other cancers in a cohort of British chemical workers exposed to formaldehyde. American Journal of Epidemiology, 179(11), 1301-1311.** Conducted an update of mortality data through 2012 for the UK cohort of 14,008 formaldehyde users and producers and reported no increased mortality from myeloid leukemia (SMR 1.16, 95% CI 0.60 -2.20 for background exposure; SMR=1.46, 95% CI 0.84 - 2.36 for low/moderate exposure; and SMR 0.93, 95% CI 0.450 -1.82 for high exposure). In a nested case-control analysis of 45 myeloid leukemias (diagnosis from underlying or contributing cause of death or as a cancer registration) and 450 controls matched on factory and age, no significantly increased risk of leukemia was seen. Although ML risk was increased (non-statistically significant) among workers exposed to high concentrations for < 1 year (OR=1.77, 95% CI 0.45 - 7.03), workers exposed to high concentrations ≥ 1 year showed no increased risk (OR 0.96, 95% CI 0.24 - 3.82)

- **Talibov, M., Lehtinen-Jacks, S., Martinsen, JI., Kjærheim, K., Lynge, E., Sparén, P., Tryggvadottir, L., Weiderpass, E., Kauppinen, T., Kyyrönen, P., Pukkala, E. (2014). Occupational exposure to solvents and acute myeloid leukemia: a population-based, case–control study in four Nordic countries Scandinavian Journal of Work, Environment & Hhealth 40.5: 511.** Analyzed 15,332 newly diagnosed cases of AML (i.e., not deaths) diagnosed from 1961 to 2005 in Finland, Norway, Sweden, and Iceland, and 76,660 matched controls. Job titles and dates of assignment were linked to a job-exposure matrix (JEM) to estimate quantitative exposure to 26 workplace agents, including formaldehyde. No association was seen between risk of AML and increasing cumulative exposure to formaldehyde, after adjusting for exposure to solvents (aliphatic and alicyclic hydrocarbon solvents, benzene, toluene, trichloroethylene, methylene chloride, perchloroethylene, other organic solvents) and radiation (HR 0.89, 95% CI 0.81 - 0.97 for workers exposed to ≤0.171 ppm-years; HR 0.92, 95% CI 0.83 -1.03 for workers

exposed to 0.171 - 1.6 ppm-yrs, and HR=1.17, 95% CI 0.91 - 1.51 for > 1.6 ppm-years, compared to workers not exposed to formaldehyde).

- **Marsh, G., Morfeld, P., Collins, J., Symons, JM. (2014). Issues of methods and interpretation in the National Cancer Institute formaldehyde cohort study. Journal of Occupational Medicine and Toxicology 9, no. 1: 1.** Evaluation concluded that efforts should be made to re-analyze data from the 2004 follow-up of the National Cancer Institute formaldehyde cohort study. The evaluation also recommended that publications resulting from the National Cancer Institute formaldehyde cohort study which contain incorrect data from the incomplete 1994 mortality follow-up should be retracted entirely or corrected via published errata in the corresponding journals. * Work supported by the ACC Formaldehyde Panel members.

- **Meyers, AR, Pinkerton, LE, Hein, MJ. (2013). Cohort mortality study of garment industry workers exposed to formaldehyde: Update and internal comparisons. AmJ IndMed 56(9):1027-39.** Updated mortality data from 1960 through 2008 for 11,043 US garment workers employed at least three months between 1955 and 1983 at three US factories and exposed to formaldehyde. A total of 36 leukemia deaths were reported (SMR=1.04, 95% CI 0.73 - 1.44, compared to US mortality rates), of which 21 were myeloid leukemia (14 AML, 5 CML, 2 other and unspecified ML). The SMR for AML was 1.22 (95% CI 0.67 - 2.05), noting that "the extended follow-up did not strengthen previously observed associations."

- **Saberi Hosnijeh, F., Christopher, Y., Peeters, P., Romieu, I., Xun, W., Riboli, E., Raaschou-Nielsen, O., Tjønneland, A., Becker, N., Nieters, A., Trichopoulou, A., Bamia, C., Orfanos, P., Oddone, E., Luján-Barroso, L., Dorronsoro, M., Navarro, C., Barricarte, A., Molina-Montes, E., Wareham, N., Vineis, P., and Vermeulen, R. (2013). Occupation and risk of lymphoid and myeloid leukaemia in the European Prospective Investigation into Cancer and Nutrition (EPIC)Occup Environ Med;70:464–470.** Studied occupational risk factors among 671 incident leukemia cases (201 ML, including 113 AML, and 237 lymphoid leukemia) in France, Oxford (UK), the Netherlands, Sweden, Norway, and Italy. Occupational exposures were estimated using a general population exposure matrix that classified occupational codes of study subjects into categories of high, low, and no exposure for 11 specific agents (e.g., benzene, trichloroethylene) or groups of agents (e.g., pesticides, chlorinated solvents). No increased risk of AML was associated with low exposure to formaldehyde (HR 1.01, 95% CI 0.65 - 1.57) and no AML cases occurred among individuals in the high formaldehyde exposure category.

Toxicological Evidence

The NAS noted the paucity of evidence of formaldehyde-induced LHP cancers in animal models. EPA's unpublished re-analysis of the Battelle chronic experiments in mice and rats (Battelle Columbus Laboratories 1981), although intriguing, provides the only positive findings and thus does not contribute to the weight of evidence of causality. Two studies, as summarized below, have been conducted by the National Toxicology Program to further evaluate the potential for LHPs in animals.

- **Morgan, DL., Dixon, D., Jokinen, MP., King, DH., Price, H., Travlos, G., Herbert, RA., French, JW., and Waalkes, MP. Evaluation of a potential mechanism for formaldehyde-induced leukemia in p53-haploinsufficient mice. (2015). Society of Toxicology Annual Meeting, Abstract #1637.** The research reported on a study testing the hypothesis that formaldehyde may cause leukemia by causing genetic damage to stem cells in the nasal epithelium or circulating in local blood vessels. Despite the fact that the study used mice pre-disposed to the development of lymphohematopoietic cancers, the results provided indicated that formaldehyde inhalation did not cause leukemia or lymphohematopoietic neoplasia in the mice. (Draft technical report currently under internal NTP review).

- **Morgan, DL., Dixon, D., Jokinen, MP., King, DH., Price, H., Travlos, G., Herbert, RA., French, JE., and Waalkes, MP. Evaluation of a potential mechanism for formaldehyde-induced leukemia in C3B6.129F1-Trp53tm1Brd mice. (2014). Society of Toxicology Annual Meeting, Poster Board -129.** Study found that no cases of leukemia or lymphohematopoietic neoplasia were seen in genetically predisposed C3B6.129F1-Trp53tm1Brd mice exposed to formaldehyde through inhalation.(Draft technical report currently under internal NTP review).

Mechanistic Evidence

The NAS noted that systemic responses are unlikely to arise from the direct delivery of formaldehyde to a distant site in the body and that the experimental evidence is insufficient to support the hypothesis that circulating hematopoietic stem cells may be the target cells for the mutagenic effects that eventually lead to cancers. The NAS also noted a need for improved understanding of exogenous and endogenous formaldehyde concentrations. Below are several studies that focus on these areas.

- **Albertini, R. J., & Kaden, D. A. (2016). Do chromosome changes in blood cells implicate formaldehyde as a leukemogen?. Critical Reviews in Toxicology, 1-40.** Research focused on the critical review and integration of the available peer-reviewed literature addressing the potential genotoxicity of formaldehyde. This publication also addresses the potential involvement of chromosome changes in blood cells suggested to be key events in proposed modes of action for the development of leukemia following formaldehyde exposure. The evaluation found reported genetic changes in circulating blood cells do not provide convincing support for formaldehyde classification as a human leukemogen. Specifically, the evaluation notes that no convincing evidence that exogenous exposures to formaldehyde alone, and by inhalation, induce mutations at sites distant from the portal of entry tissue as a direct DNA reactive mutagenic effect – specifically not in the bone marrow. In addition, recent studies reporting changes in human bone marrow or hematopoietic precursor cells either have had confounding exposures or could not distinguish in vivo from in vitro occurrences. *Work supported by the ACC Formaldehyde Panel members.

- **Lai, Y., Yu, R., Hartwell, H. J., Moeller, B. C., Bodnar, W. M., & Swenberg, J. A. (2016). Measurement of Endogenous versus Exogenous Formaldehyde–Induced DNA–Protein Crosslinks in Animal Tissues by Stable Isotope Labeling and Ultrasensitive Mass Spectrometry. Cancer Research, 76(9), 2652-2661.** Examined the formation, accumulation, and hydrolysis of DNA-protein crosslinks of both exogenous and endogenous formaldehyde. The results show that inhaled formaldehyde only reached rat and monkey noses, but not tissues distant to the site of initial contact. *Work supported by the ACC Formaldehyde Panel members.

- **Yu, R., Lai, Y., Hartwell, H. J., Moeller, B. C., Doyle-Eisele, M., Kracko, D., Bodnar, W., Starr, T., & Swenberg, J. A. (2015). Formation, accumulation, and hydrolysis of endogenous and exogenous formaldehyde-induced DNA damage. Toxicological Sciences, 146(1), 170-182.** Evaluated the plausibility for inhaled formaldehyde to reach distal sites in rat and monkey models. The study indicated that inhaled formaldehyde was found to reach nasal respiratory epithelium, but not other tissues distant to the site of initial contact. *Work supported by the ACC Formaldehyde Panel members.

- **Edrissi, B., Taghizadeh, K., Moeller, B., Kracko, D., Doyle-Eisele, M., Swenberg, J., and Dedon, P. (2013). Dosimetry of N 6-Formyllysine Adducts Following [13C2H2]-Formaldehyde Exposures in Rats. Chemical Research in Toxicology 26, no. 10: 1421-1423.** The research found that Exogenous N6-formyllysine was detected in the nasal epithelium, but was not detected in the lung, liver, or bone marrow. Endogenous adducts dominated at all exposure

conditions, The results parallel previous studies of formaldehyde-induced DNA adducts. *Work supported by the ACC Formaldehyde Panel members.

- **Gentry, R., Rodricks, J., Turnbull, D., Bachand, A., Van Landingham, C., Shipp, A., Albertini, R., and Irons, R. (2013). Formaldehyde exposure and leukemia: Critical review and reevaluation of the results from a study that is the focus for evidence of biological plausibility. Critical Reviews in Toxicology 43, no. 8: 661-670.** A critical review of the study, as well as a reanalysis of the underlying data, was performed and the results of this reanalysis suggested factors other than formaldehyde exposure may have contributed to the effects reported. Specifically, in the original study the authors did not follow their stated protocol and evaluation of the other study data indicates that the aneuploidy measured could not have arisen in vivo, but rather arose during in vitro culture. The results of the critical review and reanalysis of the data do not support a mechanism for a causal association between formaldehyde exposure and myeloid or lymphoid malignancies. *Work supported by the ACC Formaldehyde Panel members.

- **Rager, J., Moeller, B., Miller, S., Kracko, D., Doyle-Eisele, M., Swenberg, J., and Fry, R. (2014). Formaldehyde-associated changes in microRNAs: tissue and temporal specificity in the rat nose, white blood cells, and bone marrow. Toxicological Sciences: 138(1):36-46. doi:10.1093/toxsci/kft267.** In this study, a multi-tiered approach was employed to enable an understanding of the genome-wide miRNA responses to formaldehyde and to establish how these responses relate to alterations in transcriptional profiles over time and in various tissues. This study found that formaldehyde inhalation exposure induces tissue and time-dependent responses at the genomic and epigenomic level. Formaldehyde exposure disrupts miRNA expression profiles within the rat nose and white blood cells but not within the bone marrow. *Work supported by the ACC Formaldehyde Panel members.

- **Rager, J., Moeller, B., Doyle-Eisele, M., Kracko, D., Swenberg, J., and Fry, R. (2013). Formaldehyde and epigenetic alterations: microRNA changes in the nasal epithelium of nonhuman primates." Environmental Health Perspectives (Online) 121, no. 3: 339.** Research found that Formaldehyde exposure significantly disrupts miRNA expression profiles within the nasal epithelium. These results provide evidence for a relationship between formaldehyde exposure and altered signaling of the apoptotic machinery, likely regulated via epigenetic mechanisms. *Work supported by the ACC Formaldehyde Panel members.

- **Lu, K., Craft, S., Nakamura, J., Moeller, B., and Swenberg, J. (2012). Use of LC-MS/MS and stable isotopes to differentiate hydroxymethyl and methyl DNA adducts from formaldehyde and nitrosodimethylamine." Chemical Research in Toxicology 25, no. 3: 664-675.** Research demonstrated that N(2)-hydroxymethyl-dG is the primary DNA adduct formed in cells following formaldehyde exposure. In addition, the study shows that alkylating agents induce methyl adducts at N(2)-dG and N(6)-dA positions, which are identical to the reduced forms of hydroxymethyl adducts arising from formaldehyde. *Work supported by the ACC Formaldehyde Panel members.

- **Moeller, B., Lu, K., Doyle-Eisele, M., McDonald, J., Gigliotti, A., and Swenberg, J. (2011). Determination of N 2-hydroxymethyl-dG adducts in the nasal epithelium and bone marrow of nonhuman primates following 13CD2-formaldehyde inhalation exposure. Chemical Research in Toxicology 24, no. 2: 162-164.** Research found that both exogenous and endogenous adducts were readily detected and quantified in the nasal tissues of both exposure groups, with an exposure dependent increase in exogenous adducts observed. In contrast, only endogenous adducts were detectable in the bone marrow, even though ~10 times more DNA was analyzed. * Work supported by the ACC Formaldehyde Panel members.

- **Andersen, M. E., Clewell, H. J., Bermudez, E., Dodd, D. E., Willson, G. A., Campbell, J. L., & Thomas, R. S. (2010). Formaldehyde: Integrating dosimetry, cytotoxicity and genomics to understand dose-dependent transitions for an endogenous compound. Toxicological Sciences, kfq303.** In this study, concentration and exposure duration transitions in formaldehyde mode of action were examined with pharmacokinetic modeling and with histopathology and gene expression in nasal epithelium from rats exposed to concentrations of up to 15 ppm formaldehyde for up to 13 weeks. The results of the study indicated that formaldehyde concentrations below 1 or 2 ppm would not increase risk of cancer in the nose or any other tissue or affect formaldehyde homeostasis within epithelial cells. * Work supported by the ACC Formaldehyde Panel members.

- **Andersen, M. E., Clewell, H. J., Bermudez, E., Willson, G. A., & Thomas, R. S. (2008). Genomic signatures and dose-dependent transitions in nasal epithelial responses to inhaled formaldehyde in the rat. Toxicological Sciences, 105(2), 368-383.** Research included repeated and acute exposure studies to assess time and concentration-dependencies of nasal responses to formaldehyde and genomic changes. The study noted that the most sensitive gene changes were associated with extracellular components and plasma membrane. There were temporal and concentration-dependent transitions in epithelial responses and genomic signatures between 0.7 and 6 ppm. * Work supported by the ACC Formaldehyde Panel members.

Dose- Response and Modeling Evidence

The NAS noted that the biologically based dose response (BBDR) model for formaldehyde is one of the best developed BBDR models to date and recommended utilizing the BBDR model in the IRIS assessment. Below are a few studies that highlight approaches for dose response analysis in line with the NAS committee recommendation.

- **Clewell et al. (2017, manuscript in preparation).** Conducted an expansion of the BBDR model to incorporate recent data published since 2011 on endogenous levels of formaldehyde. *Work supported by the ACC Formaldehyde Panel members.

- **Van Landingham, C., Mundt, K. A., Allen, B. C., and Gentry, P. R. (2016). The need for transparency and reproducibility in documenting values for regulatory decision making and evaluating causality: The example of formaldehyde. Regulatory Toxicology and Pharmacology, 81, 512-521.** This evaluation was in response to the NAS comment to conduct independent analysis of the dose-response models used in the IRIS assessment to confirm the degree to which the models fit the data appropriately The authors reported that the documentation of the methods applied in the EPA IRIS assessment lacks sufficient detail for duplication of the unit risk estimates provided, even with the availability of the raw data from the Beane Freeman et al. (2010). This lack of transparency and detail may result in different estimates of unit risks, especially as initial analyses resulted in a lack of a significant dose-response relationship for selected endpoints. *Work supported by the ACC Formaldehyde Panel members.

- **Starr, T. B., & Swenberg, J. A. (2016). The bottom-up approach to bounding potential low-dose cancer risks from formaldehyde: An update. Regulatory Toxicology and Pharmacology, 77, 167-174.** Updated a previously proposed method (Starr and Swenberg 2013). This approach has useful applications for substances, like formaldehyde, where there is a substantial endogenous exposure in potential target tissues and little or no empirical evidence of a positive dose-response at low exogenous exposure levels. It also provides valid bounding estimates of added risk from exposure to all airborne formaldehyde concentrations up to and including 2 ppm. *Work supported by the ACC Formaldehyde Panel members.

- **Schroeter, J., Campbell, J., Kimbell, J., Conolly, R., Clewell, H., and Andersen, M. (2014) "Effects of endogenous formaldehyde in nasal tissues on inhaled formaldehyde dosimetry predictions in the rat, monkey, and human nasal passages." Toxicological Sciences 138, no. 2 (2014): 412-424.** Pharmacokinetic modeling was conducted to evaluate the impact of endogenous concentrations of formaldehyde at the portal of entry. Endogenous formaldehyde in nasal tissues did not significantly affect flux or nasal uptake predictions at exposure concentrations > 500 ppb; however, reduced nasal uptake was predicted at lower exposure concentrations.

- **Starr, T. B., & Swenberg, J. A. (2013). A novel bottom-up approach to bounding low-dose human cancer risks from chemical exposures. Regulatory Toxicology and Pharmacology, 65(3), 311-315.** Provided a refined approach for conducted risk extrapolations using a bottom up instead of top-down risk calculation. Results indicate that top-down risk extrapolations from occupational cohort mortality data for workers exposed to formaldehyde are overly conservative by substantial margins. *Work supported by the ACC Formaldehyde Panel members.

Critical Reviews and Data Integration Evidence

The NAS committee indicated that the IRIS assessment should review the discussion of asthma causation and the selected approach to establish the points of departure. The NAS also recommended that the IRIS program overall should provide more clarity in the evaluation and integration of the scientific evidence. Below are a few articles that inform the formaldehyde science in line with the NAS committee recommendations.

- **Golden, R., and Holm, S. (2017, in press). Indoor Air Quality and Asthma: Has Unrecognized Exposure to Acrolein Confounded Results of Previous Studies? Dose Response Journal.** The evaluation illustrated that there is no evidence that indicates increased sensitivity to sensory irritation to formaldehyde in people often regarded as susceptible such as asthmatics. Suggest that previous studies on potential risk factors and childhood asthma may be confounded by formaldehyde acting as an unrecognized proxy for acrolein. *Work supported by the ACC Formaldehyde Panel members.

- **Nielsen, G.D., Larsen, S.T. and P. Wolkoff. (2016) Re-evaluation of the WHO (2010) formaldehyde indoor air quality guideline for cancer risk assessment. Arch. Toxicol. doi:10.1007/s0204-016-7133-8.** Provides a summary of new key studies conducted since 2013, which were evaluated and compared to the WHO guideline. The authors concluded the overall the credibility of the WHO guideline (that recognizes threshold effects for any potential carcinogenic responses) has not been challenged by new studies.

- **Rhomberg, L. (2015). Contrasting directions and directives on hazard identification for formaldehyde carcinogenicity." Regulatory Toxicology and Pharmacology: RTP 73, no. 3: 829-833.** The article examined two separate National Academy of Sciences committee evaluations on whether formaldehyde should be identified as a human carcinogen. It highlighted key differences in the approaches, scientific methods and criteria used by two government agencies in identifying and classifying human carcinogens. It also discussed the importance of clear processes for evaluating science and how the available formaldehyde science illustrates the contrast between the two approaches when evidence is integrated to reach conclusions on hazard. *Work supported by the ACC Formaldehyde Panel members.

- **Swenberg, J., Moeller, B., Lu, K., Rager, J., Fry, R., and Starr, T. (2013). Formaldehyde Carcinogenicity Research 30 Years and Counting for Mode of Action, Epidemiology, and Cancer Risk Assessment. Toxicologic Pathology 41(2):181-189. doi:10.1177/0192623312466459.** Article reviews the data for rodent and human carcinogenicity, early mode of action studies, more recent molecular studies of both endogenous and exogenous DNA adducts, and epigenetic studies. It goes on to demonstrate the power of these research studies to provide critical data to improve our ability to develop science-based cancer risk assessments, instead of default approaches. *Work Supported by the ACC Formaldehyde Panel members.

- **Checkoway, H., Boffetta, P., Mundt, D., and Mundt, K. (2012). Critical review and synthesis of the epidemiologic evidence on formaldehyde exposure and risk of leukemia and other lymphohematopoietic malignancies." Cancer Causes & Control 23, no. 11: 1747-1766.** Evaluation found that there is no consistent or strong epidemiologic evidence that formaldehyde is causally related to any of the lymphohematopoietic malignancies. Specifically, the evaluation noted that findings from occupational cohort and population-based case-control studies were very inconsistent for lymphohematopoietic malignancies, including myeloid leukemia. Apart from some isolated exceptions, relative risks were close to the null, and there was little evidence for dose-response relations for any of the lymphohematopoietic malignancies. *Work supported by the ACC Formaldehyde Panel members.

- **Rhomberg, L., Bailey, L., Goodman, J., Hamade, A., and Mayfield, D. (2011). Is exposure to formaldehyde in air causally associated with leukemia?—A hypothesis-based weight-of-evidence analysis. Critical Reviews in Toxicology 41, no. 7: 555-621.** The evaluation concluded that the case for a causal association is weak and strains biological plausibility. *Work Supported by the ACC Formaldehyde Panel members.

- **Golden, R. (2011). Identifying an indoor air exposure limit for formaldehyde considering both irritation and cancer hazards. Critical Reviews in Toxicology 41, no. 8: 672-721.** The assessment concluded that a formaldehyde indoor air limit of 0.1 ppm should protect even particularly susceptible individuals from both irritation effects and any potential cancer hazard. *Work supported by the ACC Formaldehyde Panel members.

Message

From: Kraft, Andrew [Kraft.Andrew@epa.gov]
Sent: 2/21/2017 7:48:30 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]
Subject: FW:
Attachments: image2017-02-21-140137.pdf; ATT00001.htm

fyi

From: Shams, Dahnish
Sent: Tuesday, February 21, 2017 2:08 PM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: Fwd:

FYI -

Integrated Risk Information System (IRIS) Program
National Center for Environmental Assessment
Office of Research and Development, U.S. EPA
O: (703) 347-0167

Begin forwarded message:

> **From:** "VA-PYS-11251-M@epa.gov" <VA-PYS-11251-M@epa.gov>
> **To:** "Shams, Dahnish" <Shams.Dahnish@epa.gov>

Message

From: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Sent: 6/5/2017 12:38:55 PM
To: Jinot, Jennifer [Jinot.Jennifer@epa.gov]
CC: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]
Subject: Fwd: overview
Attachments: formaldehyde_assessment overview_052217teamreview060217.docx; ATT00001.htm

Jennifer:

I have a favor to ask. Could you look at the numbers in the last row in Table 57 of the attached where I am comparing with those from your analysis? I am afraid they may not be correct. I must have used some old numbers from you. I am driving back from Philly and will be in around 11:00.

Ravi.

Ravi Subramaniam/ Chief, Toxic Effects Branch, IRIS, NCEA, USEPA
703-347-8606 (O), 571-305-3601 (M)

Begin forwarded message:

> **From:** "Kraft, Andrew" <Kraft.Andrew@epa.gov>
> **To:** "Subramaniam, Ravi" <Subramaniam.Ravi@epa.gov>
> **Subject: Re: overview**
>
> Sorry! I must have sent before it finished loading.

From: Subramaniam, Ravi
Sent: Friday, June 2, 2017 5:08 PM
To: Kraft, Andrew
Subject: RE: overview

Hey Andrew

This email had no attachment in it!

--Ravi.

Ravi Subramaniam, PhD / Chief, Toxic Effects Branch-IRIS, NCEA-ORD, EPA.
Room PYS-11782/ **Ph: (703) 347-8606 (o); (571) 305-3601 (m)**

From: Kraft, Andrew
Sent: Friday, June 02, 2017 3:45 PM
To: Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>
Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>
Subject: overview

Hi Ravi,

Please use this version- you are the only team member still working in this document, so feel free to work with it offline. Please send it back by COB Monday or first thing in the morning on Tues. thanks!

-Andrew

Regulatory Toxicology and Pharmacology 81 (2016) 512–521

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

The need for transparency and reproducibility in documenting values for regulatory decision making and evaluating causality: The example of formaldehyde

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ARTICLE INFO

Article history:
Received 15 July 2016
Received in revised form
17 October 2016
Accepted 18 October 2016
Available online 19 October 2016

Keywords:
Reproducibility
Dose-response analysis
Formaldehyde
Inhalation unit risk estimates
Quantitative methods
Epidemiology

ABSTRACT

Reproducibility and transparency in scientific reporting is paramount to advancing science and providing the foundation required for sound regulation. Recent examples demonstrate that pivotal scientific findings cannot be replicated, due to poor documentation or methodological bias, sparking debate across scientific and regulatory communities. However, there is general agreement that improvements in communicating and documenting research and risk assessment methods are needed. In the case of formaldehyde, the peer-review conducted by a National Academy of Sciences (NAS) Committee questioned the approaches used by the Integrated Risk Information System (IRIS) in developing draft unit risk values. Using the original data from the key study (Beane Freeman et al., 2009) and documentation provided in the draft IRIS profile, we attempted to duplicate the reported inhalation unit risk values and address the NAS Committee's questions regarding application of the appropriate dose-response model. Overall, documentation of the methods lacked sufficient detail to allow for replication of the unit risk estimates, specifically for Hodgkin lymphoma and leukemias, the key systemic endpoints selected by IRIS. The lack of apparent exposure-response relationships for selected endpoints raises the question whether quantitative analyses are appropriate for these endpoints, and if so, how results are to be interpreted.

1. Introduction

Reproducibility and transparency in scientific research and reporting, both in the published literature and in documentation of decisions related to public health reached by authoritative bodies, have received significant discussion and debate (Bustin and Nolan, 2015; Campbell, 2014; Iqbal et al., 2016; Jilka, 2016). The National Institutes of Health (NIH) are exploring ways to provide greater transparency of the data that are the basis for published manuscripts (Collins and Tabak, 2014) and have noted that the greater scientific community must take steps to correct this issue. In addition, recent commentaries and surveys highlight the growing lack of reproducibility in scientific research (Anonymous, 2016). One of the most immediate and impactful consequences for a lack of transparency or reproducibility is in the direct reliance on published but un-replicated scientific findings for human health risk assessment, including the derivation of cancer unit risk estimates.

In 2011, the National Research Council (NRC) of the National Academy of Sciences (NAS) convened a Committee to Review USEPA's Draft of the *Toxicological Review of Formaldehyde – Inhalation Assessment* in support of the Integrated Risk Information System (IRIS) (NRC, 2011). The Committee noted:

> *"Problems with clarity and transparency of the methods appear to be a repeating theme over the years, even though the documents appear to have grown considerably in length"*

A further review of the IRIS process in 2014 (NRC, 2014) noted progress in meeting the NRC (2011) recommendations, but further noted:

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http://dx.doi.org/10.1016/j.yrtph.2016.10.011
0273-2300/

"However, NRC committees have conducted several reviews of some of the more complex and challenging IRIS assessments in the last decade and have identified methodologic problems and pointed out deficiencies in EPA's approaches."

Formaldehyde provides one such complex database that introduces significant challenges for consideration in a standard IRIS assessment. It is an endogenously generated compound and, for selected endpoints, multiple studies provide inconsistent results, a few of which have suggested associations with formaldehyde exposure. Some have interpreted these findings (generally at face value and apart from the larger body of results) as reflecting causal associations. As an example, there has been much scientific debate regarding whether there is a causal association between formaldehyde exposure and selected lymphohematopoietic (LHP) endpoints, especially acute myeloid leukemia. Multiple authoritative bodies (IARC, 2012; NTP, 2014) have made hazard classification decisions (sufficient evidence in humans, known to be a human carcinogen) based on conclusions that the available evidence is sufficient to conclude that there is a causal association. For the LHP cancers, these conclusions have been based on the grouping of different types of cancers from a limited number of epidemiological studies (Zhang et al., 2009; Beane Freeman et al., 2009), with little or no consideration of findings reported in many other studies or the animal or mechanistic information, much of which lends no support for or even contradicts these conclusions. It is important to note that in reviewing the same critical studies for formaldehyde as IARC (2012) and NTP (2014), the European Chemicals Agency (ECHA, 2011) concluded that

"Altogether, in absence of convincing evidence for a biologically plausible mechanism and considering the discrepancy of results in epidemiological studies, a causal relationship between formaldehyde exposure and induction of myeloid leukaemia cannot be concluded."

The 2010 draft IRIS *Toxicological Review of Formaldehyde – Inhalation Assessment* provided the first quantitative estimates of a dose-response relationship between two lymphohematopoietic endpoints, Hodgkin lymphoma (HL) and all leukemias (combined category), and exposure to formaldehyde based on the results from a single epidemiological study (Beane Freeman et al., 2009). The use of these two endpoints by USEPA (2010) for the estimation of unit risk factors was based on the conclusion that the weight of the epidemiologic evidence supported a link between formaldehyde exposure and LHP cancers, particularly myeloid leukemias. In addition to HL largely being considered unrelated to environmental exposures, no other key epidemiological study demonstrates such an association, raising questions as to the validity of the finding in Beane Freeman et al. (2009). As for the combination of all leukemias, little scientific basis is provided for aggregating what increasingly are understood to be diverse diseases with different etiologies, prognoses and treatments.

In 2011, the NRC Committee review noted many uncertainties in the approach used by USEPA (2010) to estimate risk values. The Committee recognized that USEPA (2010) had relied upon selected associations reported between formaldehyde and various LHP cancers from a single study (Beane Freeman et al., 2009). The NRC (2011) Committee further recommended that USEPA conduct an independent analysis of the dose-response models to confirm the degree to which the models fit the data appropriately, as well as consider the use of alternative extrapolation models for the analysis of the cancer data. The NRC (2011) Committee concluded that this is especially important, given the use of a single study, the inconsistencies in the exposure measures, and the uncertainties associated with the selected cancers. In addition to the impact of these assumptions, the NRC (2011) Committee noted that while the National Cancer Institute (NCI) cohort studies, including Beane Freeman et al. (2009), may be the only studies with sufficient exposure and dose-response data needed for risk estimation, they are not without weaknesses and these need to be considered. This recommendation from the NRC (2011) Committee raised several challenges. While there is some guidance provided for the use of animal data for dose-response modelling (USEPA, 2012), the use of epidemiological data in the estimation of inhalation unit risk (IUR) estimates does not have guidance that provides a "road map" for conducting these types of assessments. When using epidemiological data for the estimation of unit risk values, more extensive documentation in the IRIS profile is needed to be able to clearly understand the data relied upon and the methods applied.

In a separate study (Checkoway et al., 2015), the raw data from the NCI cohort study (Beane Freeman et al., 2009) were obtained through a Technology Transfer Agreement (TTA) with the objective of replicating the findings reported by Beane Freeman et al. (2009), as well as conducting additional analyses not reported by Beane Freeman, specifically, acute myeloid leukemia (AML). The availability of these data provided an opportunity to attempt to replicate the unit risk estimates derived by USEPA (2010), as well as address some of the questions raised by NRC (2011). In addition, it offered the opportunity to conduct alternate independent analyses to evaluate specific leukemias, rather than all leukemias combined, and the impact of alternate dose-response models on the estimates of inhalation unit risk. The methods and results of the attempt to duplicate the USEPA (2010) unit risk values, as well as conduct alternate and independent analyses to address the questions raised by NRC (2011) are reported here.

2. Methods

2.1. Duplication of USEPA (2010) reported unit risks

Our goal was to follow the same process and methods used by USEPA (2010) in the estimation of unit risk factors for the two LHP cancers (Hodgkin Lymphoma and all leukemias (combined category)). However, as noted by NRC (2011), the documentation provided in USEPA (2010) related to the assumptions and processes used in the estimation of the unit risk values was limited. NRC (2011) has outlined five steps that it appears USEPA (2010) used in the estimation of formaldehyde unit risks:

1. Evaluate the association between formaldehyde exposure and LHP endpoints;
2. Convert the relative risk estimates into lifetime risk for the exposed population;
3. Compute lifetime risks for Hodgkin Lymphoma and/or all leukemia for the unexposed population;
4. Determine the maximum likelihood and lower bound estimates of the point of departure; and
5. Estimate inhalation unit risks.

Using these five steps, we attempted to duplicate the USEPA (2010) reported unit risks for Hodgkin lymphoma and "all leukemias" using the raw data from the Beane Freeman et al. (2009) study. In order to conduct this estimate, the following were needed:

- *An estimate of cumulative dose for each individual in the cohort.* This information was not provided in either USEPA (2010) or Beane Freeman et al. (2009) and must be determined from the raw data.

- *Person time at risk for each individual.* Also not provided in USEPA (2010) or Beane Freeman et al. (2009) and must be determined from the raw data.

Absent this necessary information and with no data available to confirm how it was used in estimating risk, assumptions were necessary that impact the estimation of parameters characterizing the relationship between dose and response.

NRC (2011) also recommended that the evaluation of the epidemiological data focus on the most specific diagnoses available. Based on this recommendation, analyses were conducted to include the consideration of individual LHPs rather than combination of endpoints (e.g. all leukemias) and evaluation of alternate dose-response models for these individual endpoints. While the impact of dose metric selection (e.g., 'peak'[1] versus cumulative) has been a point of discussion in interpretation of the NCI cohort (Checkoway et al., 2015), specifically the lack of actual peak measures or estimates, the USEPA (2010) has noted that cumulative exposure is generally the preferred metric for quantitative risk assessment and was relied upon for the estimation of unit risk values. Therefore, the analyses reported below focused on cumulative exposure estimates based on the data obtained through the TTA and reported in Beane Freeman et al. (2009) and Checkoway et al. (2015).

2.2. Evaluation of model selection

NRC (2011) noted that information was needed on the degree to which the model used (i.e., Poisson regression model) fits the data, especially for dose-response analysis. NRC (2011) further noted that this type of analysis is essential because dose-response models for risk estimation must fit the data well in the low-dose range and alternative extrapolation models, including Cox regression models and nonlinear model forms, should be considered in order to identify the best-fitting model. We conducted additional analyses to evaluate the potential impact of NRC (2011) comments on both the methods and the data relied upon for unit risk estimation, as well as consideration of multiple models. In addition to a Poisson regression model, the logistic regression model was considered, as well as a Cox regression model that was applied to the data from Beane Freeman et al. (2009) by Checkoway et al. (2015). All models used a 2-year lag for exposure, which is consistent with a lag considered by both Beane Freeman et al. (2009) and Checkoway et al. (2015).

A log-linear Poisson model, which is the model reported by Beane Freeman et al. (2009) to estimate the exposure-response relationship (β values), was used to compare the results in this analysis to the results published in Beane Freeman et al. (2009) in which the cumulative 2-year lag exposure variable was categorized into discrete exposure variables using the 4 categories reported (0 ppm-years, >0 and < 1.5 ppm-years, ≥1.5 and < 5.5 ppm-years, and ≥5.5 ppm-years). A log-linear Poisson model was also fit using the discrete dose categories reported by Checkoway et al. (2015) (<0.5 ppm-years, ≥0.5 and < 2.5 ppm-years, and ≥2.5 ppm-years). In addition, both a log-linear Poisson model and a logistic regression model were fit to the data using a categorization scheme for the 2-year lag cumulative dose that split the data into quartiles so that an approximately equal number of subjects were in each group (<0.05 ppm-years, ≥ 0.05 and < 0.4 ppm-years, ≥0.4 and < 2.4 ppm-years, and ≥2.4 ppm-years). All models were run considering person-time at risk, sex and race and adjusted for pay type (i.e., hourly vs. salary). For the logistic and Poisson models, quadratic terms for exposure were also considered. For evaluation of potential model fit to the data in the low concentration region, a visual examination of the Poisson and log-logistic model estimates were compared to the case status at the end of follow-up for each individual, again considering person-time at risk, sex, race and pay type.

[1] The 'peak' exposure metric used in Beane Freeman et al. (2009) is a relative peak estimator described in Stewart et al., 1986.

3. Results

3.1. Duplication of USEPA (2010) reported unit risks

3.1.1. Step 1 – evaluate the association between formaldehyde exposure and LHP endpoints

The attempt to estimate the unit risks reported in USEPA (2010) was initiated using the model parameters (β parameters from the log-linear Poisson regression model) provided to USEPA via personal communication by Dr. Laura Beane Freeman. The β parameters describe the relationship between exposure and response. Prior to estimating the unit risk, using the raw data, we attempted to replicate the model parameter estimates provided to the USEPA (2010) by Dr. Beane Freeman using log-linear Poisson regression, which is the same modelling approach reported to have been used to develop these estimates in both the Beane Freeman et al. (2009) publication and in the draft IRIS evaluation (USEPA, 2010) (Table 1). In addition, Cox and logistic regression models were considered.

Since cumulative exposure was the focus of the USEPA (2010) unit risk estimates, an initial analysis to evaluate the association between this exposure metric and the two endpoints relied upon for unit risk estimates (i.e., Hodgkin lymphoma and all leukemias combined) was conducted. Several variables were needed from the raw data, including the estimate of cumulative exposure (ppm) for each individual and person time at risk for each individual, neither of which are provided in USEPA (2010) or Beane Freeman et al. (2009) and had to be estimated from the raw data. In addition, in order to estimate the β parameters, the raw data regarding the number of deaths from a specific cancer and corresponding exposure metric must be divided into the same exposure quartiles as those reported by Beane Freeman et al. (2009) to evaluate the exposure-response relationship.

For the current analyses, the following steps were conducted to identify the data needed for analysis.

1. Using the work history data and date of birth, the data records were combined and organized to result in one or more record for each job so that no record spanned a calendar year or a change in age. Calculation of the duration of each work record was performed in this step with consideration of leap years. Since only start and stop months of work were provided in the raw data from Beane Freeman et al. (2009), the initial start and final stop day for a job were assumed to be the 15th of the month unless the start and stop months were the same month in the same year. In this case, the stop day was assumed to be the appropriate value for the end of the month (28, 29, 30 or 31). The gender, race, salary code and status of each individual (alive or dead) and cause of death ICD code were also attached to the individual's record.
2. The exposure and duration of exposure were summed over the months in a year when the individual was a specific age. During this step, the peak exposure category for each work record was determined.
3. The cumulative and lagged cumulative exposure and person-years of exposure were calculated.
4. The records were categorized into the strata of ranges of years (groups covering a 5 year period starting with 1960 and ending

Table 1
Comparison of modelling statistics from the current analysis to statistics reported in USEPA (2010).

	Current analysis												USEPA (2010)		
	Cox regression			Logistic regression					Poisson regression						
	p-value [a]	β (per ppm x year)	Standard error (per ppm x year)	R^2	LR p-value[b]	p-value [a]	β (per ppm × year)	Standard error (per ppm × year)	LR p-value[b]	p-value [a]	β (per ppm × year)	Standard error (per ppm × year)	p-value	β (per ppm × year)	Standard error (per ppm × year)
Hodgkin lymphoma (201)	0.013	0.0294	0.0119	0.0133	0.098	0.019	0.0288	0.0123	0.09	0.037	0.0243	0.0117		0.02959	0.01307
Leukemia (204–207)	0.058	0.0117	0.0062	0.0017	0.35	0.055	0.0121	0.00628	0.003	<0.001	0.0206	0.0057	0.08	0.01246	0.000642
Leukemia (204–207, excluding 204.1)	0.239	0.0092	0.0079	0.0011	0.64	0.206	0.01	0.00791	0.034	0.013	0.018	0.0073	–	–	–
Acute myeloid leukemia (205.0)	0.844	−0.004	0.0201	0.0016	0.82	0.869	−0.0032	0.0196	0.81	0.80	0.0045	0.0179	–	–	–

Cox regression model $h(t,x) = h_0(t)\ exp(\beta x + \gamma z)$.
Logistic regression model $Y = 1/[1 + exp(-\alpha + \beta x + \gamma z)]$.
Poisson regression model $Ln(Y/t) = \alpha + \beta x + \gamma z$ OR $Y = t\ exp(\alpha) \times exp(\beta x)) \times exp(\gamma z)$.
Where Y is the expected number of events, α is the intercept, β is the slope term, x is the exposure, z is a covariate and t is the duration of exposure. In the Cox model h is the hazard rate.
[a] These p-values reflect the precision of any association between exposure and response, and show the probability that the beta value is not significantly different from zero. P-values < 0.5 indicate that the beta parameter is significantly different from zero.
[b] The likelihood ratio p-values of difference between a null and dose-dependent model (e.g. test of β = 0) where small p-values reject the hypothesis that β = 0.

with 2010), and age groups (groups covering a 5 year range starting with the age of 15 and ending with 85), where the lowest year group included all records prior to 1965, and the 1965 group included years 1965 through 1969, with all job records occurring in 2010 and after included in the 2010 category. For ages, all ages less than 20 were included with the 15 year old age group, and the second group labelled 20 included all ages from 20 through 29.

5. The final record for each individual included an indication of dead or alive. For those individuals who had died, the ICD codes were used to set up yes/no flags indicating whether Hodgkin lymphoma, leukemia or acute mylogenous leukemia were found in that individual.

This process resulted in 1,047,291 work records that were then used in the analyses. All analyses used stratification for age group, year group, gender and race, with all the models adjusted for salary type treated as a classification variable. The Poisson analysis (SAS Proc Genmod) used a Poisson distribution, a log link and an offset of the natural log of the cumulative person-years of exposure. SAS Proc Logistic was used to perform the logistic regression and Cox proportions hazards models were performed using STATA (Checkoway et al., 2015).

Beane Freeman et al. (2009) reported that the cut points for the exposure groups were based on the approximate 60th and 80th percentiles from the cumulative exposures for those subjects with cancer. In attempting to duplicate the number of cancers within each exposure group, the cut points of 1.5 and 5.5 ppm-years (cumulative exposure groups defined by Beane Freeman et al. (2009) as ≤0 to 1.5, 1.5 to <5.5, ≥5.5 ppm-years) could not be duplicated based on the estimated 60th and 80th percentiles using the raw data. The calculations for the current assessment resulted in the determination of 1.2 and 4.2 ppm-years as the 60th and 80th percentiles for the cumulative exposure of the subjects with cancer. In addition, the number of unexposed workers (4359) reported by Beane Freeman et al. (2009) could not be replicated. Using the raw data, only 2676 unexposed workers could be identified.[3]

Regardless of the lack of ability to duplicate this determination of exposure, an evaluation of the exposure-response relationship was conducted. For the "all leukemia" category, exposure-response was evaluated including and excluding chronic lymphocytic leukemia (CLL), because, as noted by Checkoway et al. (2015), CLL has been classified as a non-Hodgkin lymphoma (NHL) since 2001 (Muller-Hermelink et al., 2001; Campo et al., 2011).

Other models were attempted in this process. Using quadratic terms for exposure failed to provide any better fit of the models to the data. In addition, the effect of exposure to other substances were explored but these did not improve the model fits substantially, either.

As noted in Table 1, in attempting to duplicate the β parameter and standard error for each cancer type, similar values could be estimated, but the estimates reported in USEPA (2010) could not be duplicated, which can impact attempting to duplicate unit risk estimates. In addition, it is important to note that no significant association between leukemia as a class of diseases (p-values > 0.05; Table 1) or specifically for acute myeloid leukemia ($p \geq 0.8$) with cumulative exposure to formaldehyde was found (using the typical 0.05 as the determinant of "significant") for either the Cox regression or the logistic regression. In addition, the estimated β parameter for acute myeloid leukemia (~-0.004 from the Cox regression and the logistic regression) indicates that the slope is in the negative direction (decreasing incidence with increasing exposure). These results for AML suggest that it would not be appropriate to rely upon these negative data independently in the dose-response modelling for the estimation of a unit "protection" estimate. As imprecise positive estimates of a β parameter should not be interpreted as evidence of risk, imprecise negative β parameters should not be interpreted as beneficial or protective. For all the logistic models, the likelihood ratio test indicates that the β parameter is not statistically different from zero. Similarly the likelihood ratio test of the Poisson models for Hodgkin lymphoma and the acute myeloid leukemia also indicate that the β parameter is not statistically different from zero. Only for the Poisson models of combined leukemias are the β values considered to be statistically significantly different from zero. However, as these are

combined types of leukemia which are not recommended by the NRC (2011) and there is almost a factor of 2 difference between the β estimates between the different models in the current analysis and the USEPA (2010) β estimate, there is still large uncertainty in the results.

The estimated β parameter for Hodgkin lymphoma was comparable to that reported in USEPA (2010); however, there was a difference in the standard error and a larger difference in the p-values. USEPA (2010) reported a non-significant trend between cumulative formaldehyde exposure and Hodgkin lymphoma based on information reported in Beane Freeman et al. (2009), while the current analysis suggested a significant trend (p-value = 0.013). These results are consistent with those reported by Checkoway et al. (2015). However, Checkoway et al. (2015) notes that the increased risk of HL has not been observed in other occupational studies of formaldehyde-exposed cohorts, and is not regarded as plausibly related to environmental chemical exposures.

Because the β parameters could not be duplicated, it was concluded that while additional steps could be conducted to evaluate the transparency of the process, the lack of ability to duplicate this first step would result in a lack of ability to duplicate the reported unit risks. Even having access to the raw data from the Beane Freeman et al. (2009) study, there were not enough details regarding the methods used to evaluate the data provided in USEPA (2010) to duplicate the initial β parameters necessary to initiate the unit risk estimate process.

3.1.2. Step 2 – convert the relative risk estimates into lifetime risk for the exposed population

Relying strictly on the β parameters reported in USEPA (2010), even though they could not be duplicated, an attempt was made to conduct the remaining steps of the estimation of unit risk as outlined by NRC (2011). USEPA (2010) noted that the β parameters were used in a life table analysis to calculate lifetime extra cancer risks from formaldehyde exposure. This step, as well as step 3, requires the use of a life-table method in conjunction with (a) the Poisson model mortality risk, (b) age-specific all-cause mortality rate in the United States population, and (c) Hodgkin lymphoma and all leukemia mortality rates, all of which can be derived from the NCI's Surveillance, Epidemiology and End Results (SEER) database. SEER collects cancer incidence data from multiple geographical areas in the United States. This step also requires estimates of the effective concentration (EC) for occupational exposure adjusted to continuous ambient exposure (the standard exposure metric relied upon by USEPA in the estimation of a unit risk) by multiplying by the ratio of days in a year to work days (240, 50 weeks of 5 day work weeks) and the ratio of daily inhalation rate (20 m^3) to work day inhalation rate (10 m^3) (USEPA, 2010).

$$EC = exposure\ (ppm) \times \frac{365}{240} \times \frac{20}{10}$$

USEPA (2010) provided a spreadsheet (Appendix C of USEPA, 2010; Supplemental Tables S1 and S2) illustrating the life table used for the extra risk calculation for the derivation of the LEC_{0005} (95% lower confidence limit on the effective concentration corresponding to an extra risk of 0.05%) relied upon for estimating the IUR based on nasopharyngeal (NPC) mortality reported by Hauptmann et al. (2004). USEPA (2010) noted that the same general methodology described for NPC mortality estimates was used for Hodgkin lymphoma and leukemias, with the following exceptions:

- U.S. age-specific 2006 all-cause mortality rates (NCHS, 2009);
- NCHS age-specific 2002–2006 background mortality rates for Hodgkin lymphoma and leukemia (http://seer.cancer.gov/csr/1975-2006/) for all race and gender groups; and
- A 2-year lag period instead of a 15-year lag period.

It is important to note that USEPA (2010) provided no citation for the NCHS (2009) all-cause mortality rates, so it was assumed this was obtained from the NCHS website (http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf) as the background mortality rates for specific cancers (Heron et al., 2006). While this does provide data needed to allow the assessor to attempt to duplicate this procedure, there is no comparable life-table for Hodgkin lymphoma or all leukemias to ensure that comparable results are achieved. Relying upon these sources and following these approaches, the IURs provided in USEPA (2010) could not be duplicated using the reported sources and methodology. This was also true for NPC for which the life table was provided (Appendix C; USEPA (2010)). In attempting to duplicate the IURs reported for NPC, it was determined that the values reported from the use of the life table instructions provided could not produce the reported IURs for NPC (see supplemental Table S1 for the re-creation of the calculations that would correspond to the unit risks reported in USEPA (2010) when using the instructions provided by USEPA (2010) for Table C-1. The difficulty in duplicating the life table reported was related to the function reported for estimating the NPC incidence hazard rate (Column L in Supplemental Table 2). Using the USEPA (2010) β of 0.0518 (SE 0.01915) and the calculations as specified in Table C-1 of USEPA (2010), the estimated EC_{0005} and LEC_{0005} would be 0.103 and 0.0623 ppm, respectively, with a unit risk of 8×10^{-3}. However, the calculations specified in Appendix C of USEPA (2010) indicated a function for the hazard incidence rate of $hx_i = h_i \times (1 + \beta \times xdose)$ which is inconsistent with the model of risk that was used to determine the β value ($RR = e^{\beta X}$, where β represents the regression coefficient for exposure and X is exposure as a continuous variable) (USEPA, 2010). When the hazard rate function is changed to $hx_i = h_i \times (e^{\beta \times xdose})$ to properly reflect the underlying risk function, the values estimated by the revised life table were the same as those reported by the USEPA in Tables 5–11 for EC_{0005} and LEC_{0005} based on NPC incidence for formaldehyde exposure (0.074 and 0.046 ppm, respectively, see supplemental Table S3 for the adjusted life-table calculation). However, it is important to note that these estimates rely upon the β parameters reported in USEPA (2010), which cannot be duplicated.

3.1.3. Step 3 – compute lifetime risks for Hodgkin Lymphoma and/or all leukemia for the unexposed population

As noted in USEPA (2010), USEPA cancer risk estimates are typically derived to represent a plausible upper bound on increased risk of cancer *incidence*, typically based on experimental animal incidence data. However, epidemiological studies more often present results based on mortality data, which is true for the Beane Freeman et al. (2009) study. For cancers with low survival rates, mortality-based estimates are a reasonable approximation of cancer incidence risk. However, USEPA (2010) largely documents its approach to the evaluation of nasopharyngeal cancers and noted the need to estimate incidence-based risks. Estimation of the incidence of a particular cancer type using mortality data can be conducted by acquiring the age-specific incidence rates for a specific cancer from the SEER program. In order to estimate the potential risk of incidence of a cancer type, the data from the SEER database are used to adjust the mortality data assuming that the exposure-response relationship for incidence and mortality of a cancer type are the same. An examination of the assumptions and adjustments made to the Beane Freeman et al. (2009) data for lymphohematopoietic cancers follows.

Table 2
Extra risk estimates for Hodgkin lymphoma mortality from various levels of continuous exposure to formaldehyde (reproduced from Tables 5–14 in USEPA (2010)).

Exposure concentration (ppm)	As reported by USEPA (2010)		Estimated using the life table provided in USEPA (2010) [a] with adjustments to the hazard function	
	Extra risk	95% UCL on extra risk	Extra risk	95% UCL on extra risk
0.0001	2.04×10^{-7}	3.53×10^{-7}	2.52×10^{-7}	4.36×10^{-7}
0.001	2.05×10^{-6}	3.55×10^{-6}	2.53×10^{-6}	4.38×10^{-6}
0.01	2.10×10^{-5}	3.71×10^{-5}	2.59×10^{-5}	4.59×10^{-5}
0.1	2.79×10^{-4}	6.17×10^{-4}	3.44×10^{-4}	7.63×10^{-4}
1	1.63×10^{-1}	8.36×10^{-1}	1.90×10^{-1}	8.53×10^{-1}
10	9.89×10^{-1}	9.90×10^{-1}	9.89×10^{-1}	9.90×10^{-1}

[a] Using the supplied information in the life table provided in USEPA (2010) with an adjustment in column L for the incidence hazard rate in interval I ($hxi = hi \times e^{(\beta \times xdose)}$) for the estimates of $\beta = 0.02959$, SE = 0.01307.

Table 3
Extra risk estimates for leukemia mortality from various levels of continuous exposure to formaldehyde (reproduced from Tables 5–15 in USEPA (2010)).

Exposure concentration (ppm)	Calculated by USEPA (2010)		Estimated using the life table provided in USEPA (2010) [a] with adjustments to the hazard function	
	Extra risk	95% UCL on extra risk	Extra risk	95% UCL on extra risk
0.0001	1.64×10^{-6}	3.02×10^{-6}	1.65×10^{-6}	3.06×10^{-6}
0.001	1.64×10^{-5}	3.03×10^{-5}	1.65×10^{-5}	3.07×10^{-5}
0.01	1.66×10^{-4}	3.10×10^{-4}	1.67×10^{-4}	3.13×10^{-4}
0.1	1.87×10^{-3}	3.90×10^{-3}	1.89×10^{-3}	3.95×10^{-3}
1	8.07×10^{-2}	5.19×10^{-1}	8.16×10^{-2}	5.28×10^{-1}
10	9.80×10^{-1}	9.89×10^{-1}	9.80×10^{-1}	9.89×10^{-1}

[a] Using US 2006 mortality rates, the adjusted life table structure and potency estimates ($\beta = 0.01246$, SE = 0.006421) from USEPA (2010).

Table 4
Relative risk based on peak exposure from Poisson model stratified by calendar year, age, sex and race and adjusted for pay category.

	0 ppm		>0 to <2.0 ppm		> = 2.0 to <4.0 ppm		> = 4.0 ppm		Log likelihood	p-value
Total in group	3139		10,302		6010		6168			
Person-years	104,386		415,987		254,723		256,618			
	Cases	RR (95% CI)	Cases	RR (referent)	Cases	RR (95% CI)	Cases	RR (95% CI)		
Hodgkin lymphoma (201)	2	3.32 (0.60–18.26)	6	1.0	8	0.76 (0.30–1.89)	11	2.96 (0.94–9.27)	−309.87	0.04
Leukemia (204–207)	7	1.83 (0.76–4.40)	41	1.0	27	0.58 (0.36–0.93)	48	0.58 (0.36–0.93)	−1177.94	0.004
Leukemia (204–207, excluding 204.1)	6	1.61 (0.61–4.24)	28	1.0	20	0.56 (0.32–0.96)	37	1.17 (0.65–2.09)	−901.65	0.009
Acute myeloid leukemia (205.0)	4	1.21 (0.33–4.43)	9	1.0	9	0.77 (0.32–1.84)	12	1.72 (0.67–4.43)	−374.47	0.34

Since USEPA's life table analysis relied upon background mortality rates to determine the extra risk from the incidence of the endpoint of interest, the effect of using background incidence data for Hodgkin lymphoma and all leukemia was explored. The background mortality rates were adjusted to reflect the background incidence of the endpoint by replacing the mortality rate attributed

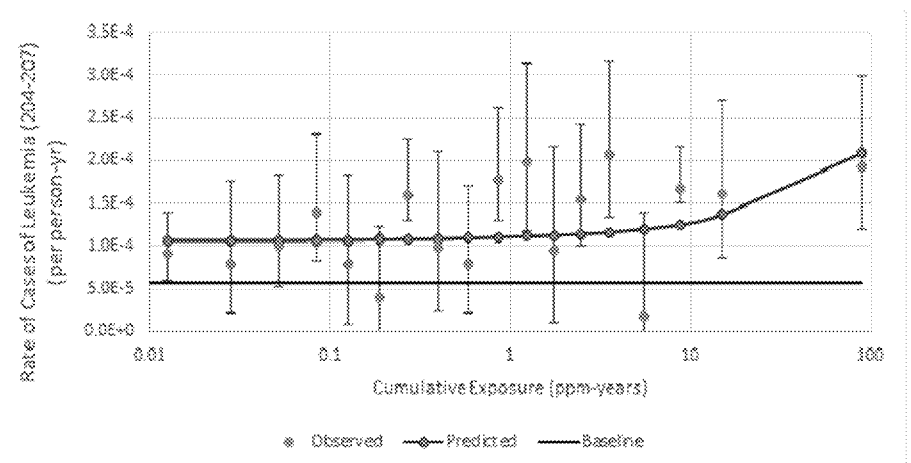

Fig. 1. Comparison of estimated cases from the Poisson regression model to number of cases of leukemia observed at the end of follow-up period in the Beane Freeman et al. (2009) study. Observed and predicted results over full observed exposure range.

to that endpoint with the incidence rate of that endpoint. Making this correction resulted in a difference of between 10 and 21% in the estimated risks for the current analysis.

3.1.4. Step 4 – determine maximum likelihood and lower bound estimates of point of departure

USEPA's carcinogenicity risk-assessment guidelines (USEPA, 2005) recommend the use of an extra risk of 1–10% for deriving effective concentration at the Point of Departure (POD), or for the USEPA (2010) IRIS assessment. NRC (2011) noted that in USEPA (2010) there was an unusual choice of a 0.05% extra risk for Hodgkin lymphoma and 0.5% extra risk for all leukemias. USEPA (2010) noted the issues with using standard extra risk levels (e.g., 10%) in that the risks using these standard extra risk assumptions resulted in relative risk estimates that were substantially higher than those observed in the epidemiology study. Therefore, the choice of the extra risk value to use was based on the background mortality rate for each individual cancer type compared to the relative risk estimates observed in the Beane Freeman et al. (2009) study. Relative risk estimates were determined starting at the 10% extra risk level, decreasing the extra risk level until the relative risk estimates were within the observable range of the epidemiology study. For example, if the 1% level of risk associated with the relative risk estimates for NPC were higher than those observed in the Beane Freeman et al. (2009) study, the extra risk level of concern was lowered until the relative risk estimates were below the relative risk estimates from the Beane Freeman et al. (2009), so an upward extrapolation could be conducted. This approach effectively assumes that nothing observed in the Beane Freeman et al. (2009) could be attributable to background incidence of these cancer types.

Using the hazard rate function as instructed in the life table example (Footnote for Column L, Table C-1 of USEPA (2010)), the extra risk and 95% upper confidence limits on extra risk provided in USEPA (2010) cannot be reproduced (Tables 2 and 3). However, using a life table that had a hazard rate function consistent with the underlying risk function produced results that were similar to those reported by the USEPA (2010). Supplemental Tables S2 and S4 show the differences in the risk values calculated at an exposure of 1 ppm using the USEPA (2010) instructions (Table S2) versus the revised life table (Table S4) with the modified hazard function that was necessary to duplicate the EC, LEC and unit risk values reported in USEPA (2010). While there was some correspondence, there were still some differences in the values that were calculated for the extra risk (Tables 2 and 3) and there is some concern about the appropriateness of the risk estimates, especially large estimates of risk for values above 0.1 ppm. An exposure of 0.1 ppm is within the range of exposures (0.01–4.3 ppm – TWA) reported by Beane Freeman et al. (2009). The relative risk values estimated for these exposures approach 100% and are inconsistent with the observed incidences of cancers in the Beane Freeman et al. (2009) study.

3.1.5. Step 5 – convert the relative risk estimates into lifetime risk for the exposed population

With the results from step 4, the lower bounds on exposure (LECx) and the extra risk level should then be used to determine the unit risks. However, because the model parameters from step 1 could not be replicated, an attempt was made to replicate the MLE and lower bounds using the USEPA (2010) reported model parameters. Using a life table analysis that follows the methods provided in Appendix C of USEPA (2010) and the reported model parameters, the MLE and lower bounds on dose for Hodgkin lymphoma and all leukemia could not be replicated. Using the available parameters and results reported in USEPA (2010) and using the USEPA's parameters, a 12–27% difference in unit risk values was determined for leukemia, Hodgkin's lymphoma and NPC from those reported by the USEPA (2010). However, when the life table was adjusted to be consistent with the relative risk model that was the basis of the β value used in USEPA (2010), the values reported by the USEPA could be replicated.

In noting the potential differences in unit risk estimation, this 12–27% difference could be considered in combination with the potential differences in unit risk from step 1 (differences in the model results), as well as the potential impact of the differences in risk from step 3. Therefore, the inability to replicate individual steps in the process may result in unit risk estimates different from those in USEPA (2010) by 100% or greater due to differences in the slope factors (up to 100% difference) as well as differences in life table analysis results (12–27%) that would be calculated following the documentation provided in USEPA (2010).

Analyses were also conducted using the "peak" exposure metric, rather than the continuous metric relied upon by USEPA (2010) for their evaluation. This was conducted using the same model (log-linear Poisson stratified by calendar year, age sex, and race and adjusted for pay category) as Beane Freeman et al. (2009), but in contrast to the results reported by Beane Freeman et al. (2009), no significant relative risks were estimated (Table 4). Reasons for the differences between the current analyses and those reported by Beane Freeman et al. (2009) could include that the specific dates of job start and job end were not provided, nor were the specific dates that follow-up started or ended: only month and year were reported.

3.1.6. Evaluation of model selection

In evaluating the potential fit of the model to the data, there are various tests that can be performed to look at the predictive power of a model (e.g. R^2 tests, χ^2 tests), to make comparison between models (e.g. AIC and other log-likelihood tests) or graphical representations of the data to visualize the fit. However, since no such statistics were provided in either Beane Freeman et al. (2009) or USEPA (2010), comparisons can only be made among the models fit to the data in this current analysis. The R^2 values reported for the logistic regression performed in this analysis were uniformly poor (i.e., 0.05 or less) indicating poor predictive ability of the models. For the Poisson models, there were small values for the Pearson χ^2 value which, with the large sample size, achieved a better fit to the data (p-values close to 1). However, in graphs presented in this analysis using the data at the end of follow-up, the rate of all leukemias was plotted against the continuous exposure as well as the model predicted rates estimated for both the Poisson regression model (Fig. 1) and the logistic model (Fig. 2).[2] These figures show large variability in the observed rates in the low concentration region which subsequently makes comparison and evaluation of the fit of the model to the data difficult. This variability also makes any predictions made with models fit to these data highly uncertain. In addition, the predictions of extra risk provided by USEPA (2010)

[2] The graphs were constructed using the 5% percentiles (e.g. 5%, 10%, 15%, etc.) of the cumulative exposure, and sums of the person-years, number of individuals and number of observed and predicted leukemias per percentile to determine the rates. The confidence limits for the logistic graph were calculated using binomial confidence limits on the observed rates of leukemia per percentile group of exposure, and the Poisson confidence limits are exact confidence limits based on the Poisson distribution.

[3] This number of unexposed workers identified in the current analysis (2676) is consistent with the number determined by Checkoway et al. (2015) in a separate reanalysis of the raw data from Beane Freeman et al. (2009) study. When this difference was discovered by Checkoway et al. (2015), communications with Dr. Beane Freeman indicated that the number of unexposed workers reported was a mistake and should have been 3,108. However, Checkoway et al. (2015) could not duplicate this number of unexposed workers either using the raw data.

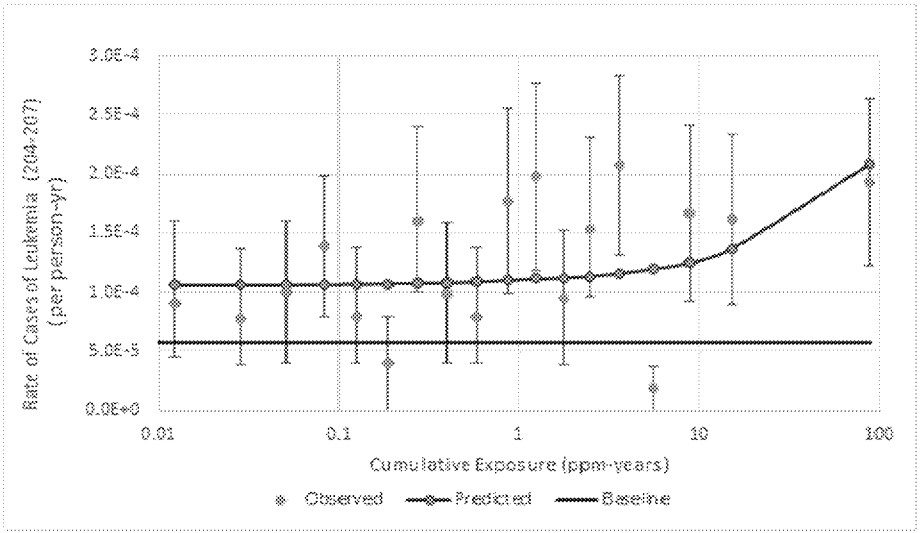

Fig. 2. Comparison of estimated cases from the logistic regression model to number of cases of leukemia observed at the end of follow-up period in the Beane Freeman et al. (2009) study. Observed and predicted results over full observed exposure range.

associated with higher concentrations (1 and 10 ppm) are above the observable range and involve upward extrapolation. The results are estimates of extra risk approaching 1, which are unreasonable.

While each model provides predictions that "run through the middle" of the data, it is clear that neither model can adequately predict the exposure-response relationships or lack of pattern in the lower concentration region (Figs. 1 and 2), as the data in this region of the exposure-response curve appears to be comparable to random variation. In the low concentration region, the data lack a clear monotonic dose-response relationship, which may explain lack of a significant trend ($p = 0.08$) even for the combination of all leukemias. Overall, the models do not fit the pattern of exposure-response in the data. While the models appear to be more consistent with the data at concentrations greater than 10 ppm-years, this comparison is largely influenced by two data points. It is possible that this shape of the exposure-response curve may explain the unusual nonlinearities in the estimates of extra risk provided by USEPA (2010) (Tables 2 and 3). However, explaining this unusual exposure-response behavior is difficult due to the inability to duplicate the unit risk estimates provided in USEPA (2010).

4. Discussion

One of the greatest challenges in attempting to duplicate unit risk factors estimated by USEPA is attempting to duplicate those specifically based on epidemiological data. When USEPA has relied upon animal data for the estimation of unit risk values, even when the documentation provided is limited, there are guidelines available (USEPA, 2012) that provide specific steps and assumptions used by USEPA in the dose-response analysis of animal data. However, when epidemiological data are applied, there is not comparable guidance, and the necessary additional detail may not be provided in the IRIS documentation to allow for transparency and the ability to duplicate risk values.

In the case of formaldehyde, the draft IRIS toxicological review (USEPA, 2010) provided documentation largely on the estimation of IURs from the cases of NPC from the NCI cohort reported by Hauptmann et al. (2004), assuming that these methods could easily be extended in an attempt to duplicate values for lymphohematopoietic cancers provided in an update to the NCI cohort by Beane Freeman et al. (2009). The results from this assessment, in attempting to duplicate unit risk values for lymphohematopoietic cancers, demonstrate that this is not the case.

Difficulty in duplication of results from each step of the process of the estimates of IURs, following the steps as outlined by NRC (2011), started with the initial step that involved duplication of the β parameters from the log-linear Poisson regression model as provided by Dr. Laura Beane Freeman to the USEPA. In the initial step of the process, our results suggest no significant association between cumulative exposure to formaldehyde, which is the exposure metric relied upon by USEPA (2010) for the estimation of the IURs, and either all leukemias combined or acute myeloid leukemia specifically. This lack of association is directly relevant to evaluation of causality and should be considered earlier in the determination of what endpoints likely are caused by exposure to formaldehyde and therefore which associations might be relied upon for the estimation of IURs. Based on the results for all leukemias, as well as AML, with no significant trends observed, it is not appropriate to conduct dose-response modelling only on null findings. In addition, while similar, the β values could not be duplicated even with the availability of the raw data, which suggests that the methods applied are not adequately documented in USEPA (2010).

USEPA (2010) relied heavily upon the Beane Freeman et al. (2009) study for risk estimation associated with lymphohematopoietic tumors, with the NRC (2011) committee noting that this may be the only study with sufficient exposure and dose-response data needed for risk estimation. However, they also noted that this study is not without weaknesses and these need to be considered. A reanalysis of the raw data from the NCI study (Beane Freeman et al., 2009) was conducted by Checkoway et al. (2015). While basic results were replicated, additional analyses of the associations of specific lymphohematopoietic cancers, specifically acute myeloid leukemia (AML) with various metrics of formaldehyde exposure (peak, average, cumulative) and using a more standard definition of peak exposure than that relied on by Beane Freeman et al. (2009) were reported. The re-evaluation highlighted many of the limitations in the data from this cohort, and the new analyses indicated no clear association with AML. It is not clear why AML results had not been reported in any of the updates of this study, and not considered in the IRIS evaluation, given that AML has been highlighted as the lymphohematopoietic cancer most likely to be

relevant to a chemical agent, primarily based on its association with benzene.

The results from the current analysis for Hodgkin lymphoma also provide estimates inconsistent with those reported by USEPA (2010). Using the cumulative exposure metric, USEPA (2010) reported no significant trend for Hodgkin lymphoma. The current analysis suggests a significant trend (Table 1 – p = 0.013), which is consistent with the results from Checkoway et al. (2015) reporting increased relative risk estimates for Hodgkin lymphoma in the highest exposure categories of cumulative and peak exposures. As noted in Checkoway et al. (2015), these findings are complicated because there is little epidemiological support for chemical exposures in the etiology of Hodgkin's lymphoma. There is an absence of an increased risk for this cancer type in other occupational cohorts, as well as the lack of a plausible biological mechanism. In addition, NTP (2014) noted that because the evidence for Hodgkin lymphoma is mainly limited to the NCI cohort study, a causal association is not established. As with all leukemias, including AML, there are questions related to a causal association between cumulative formaldehyde exposure and this cancer type that suggest that the estimation of a quantitative measure of risk using these data are inappropriate.

NRC (2011) also highlighted that the modes of action for formaldehyde-induced Hodgkin lymphoma and for leukemias have not been established. Moreover, the studies that demonstrate the lack of systemic delivery of formaldehyde following inhalation exposure (Lu et al., 2011; Moeller et al., 2011; Edrissi et al., 2013; Yu et al., 2015) draw into question the biological plausibility of formaldehyde causing any LHP cancer. NRC (2011) noted that

> *"Although EPA postulated that formaldehyde could reach the bone marrow either as methanediol or as a byproduct of nonenzymatic reactions with glutathione, numerous studies described above have demonstrated that systemic delivery of formaldehyde is highly unlikely at concentrations below those which overwhelm metabolism according to sensitive and selective analytic methods that can differentiate endogenous from exogenous exposures."*

Thus, substantial uncertainties remain in using both Hodgkin lymphoma and leukemias (all or individual) for consensus cancer risk estimation. Formaldehyde is rapidly metabolized and highly reactive and, because it is an endogenous compound, a detectable change in the natural background or endogenous levels would need to occur in order to result in the potential for adverse effects. Multiple studies using multiple species, including non-human primates, have been conducted using a sensitive analytical method that can measure endogenous versus exogenous formaldehyde DNA adducts (Yu et al., 2015; Edrissi et al., 2013; Moeller et al., 2011; Lu et al., 2011). The results of these studies indicated that inhaled formaldehyde was found to reach nasal respiratory epithelium, but not other tissues distant to the site of initial contact. These results suggest a lack of an ability for exogenous or inhaled formaldehyde exposure to affect endogenously present concentrations of formaldehyde.

Although the Draft Review cites hypotheses proposed by Zhang et al. (2010) regarding the theoretical development of leukemia following inhalation of formaldehyde, there is no documented evidence to support the validity of these hypotheses. In fact, Zhang et al. (2010) note that their hypotheses related to mechanisms of leukemia clearly require additional testing. The existing mechanistic data for formaldehyde provide no evidence that exogenous formaldehyde will be transported from the point of contact to distant sites, but do provide evidence that formaldehyde does not affect the relevant target cells for leukemia (bone marrow or peripheral blood) (Yu et al., 2015; Edrissi et al., 2013; Moeller et al., 2011; Lu et al., 2011).

Overall, the documentation of the methods applied by USEPA lacks sufficient transparency and detail for duplication of the unit risk estimates provided in USEPA (2010), even with the availability of the raw data from the Beane Freeman et al. (2009) study that USEPA relied upon for estimation of the risk of Hodgkin lymphoma or all leukemias. This lack of transparency and detail may result in different estimates of unit risks, including invalid estimates, especially as initial analyses resulted in a lack of a significant dose-response relationship for selected endpoints.

In attempting to duplicate the USEPA (2010) calculations, difficulties were encountered at each step, largely due to a lack of critical information provided in the IRIS documentation. Even though analyses were conducted multiple times with different assumptions, all of which could be consistent with the description provided by USEPA (2010), the unit risk values could not be duplicated. The results of the analyses yielded conflicting and different estimates with each step of the analysis, with differences in each step up to a factor of 2. The inability to replicate individual steps in the process may result in unit risk estimates different from those in USEPA (2010) by 100% or greater due to differences in the slope factors (up to 100% difference) as well as differences in life table analysis results (12–27%). Perhaps most problematic, the first step of the analysis did not determine significant exposure-response relationships between formaldehyde and LHP endpoints for the metric (cumulative exposure) needed in the estimation of an IUR. The resulting analysis, while it can be mechanically performed, provides no valid or useful insights on the risks of formaldehyde exposure. Regulatory dependence on these analyses may therefore lead to erroneous guidance, policies and laws.

These results highlight the necessity of clear and transparent reporting of both methods and data used in the estimation of unit risk values. Values provided by the IRIS program of USEPA are relied upon by other federal and state agencies in regulatory decision-making related to the development of standards and guidelines for environmental, consumer product and workplace exposure to chemicals. The inability to duplicate these types of values only escalates the scientific debate over the applicability of these standards and the scientific data necessary to support conclusions regarding acceptable levels of human exposure to chemicals.

Acknowledgements

This project was supported by funding provided by the Research Foundation for Health and Environmental Effects (Contract number R0072). RFHEE is a 501(c) (3) tax-exempt organization established by the American Chemistry Council (ACC). Established in 1995, RFHEE works to address uncertainties and answer questions on health and environmental issues related to the production and use of chemistry. RFHEE works with industry, public agencies, academia and other foundations on projects that will furnish crucial information, peer-reviewed scientific research, expert panels, and workshops that will provide information for public policy. RFHEE receives contributions from government, industry (companies and trade organizations), and other industry partners who share its commitment to improving the factual and scientific understanding about critical questions associated with and/or impacting chemistry. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of any manuscript. The funders were given the opportunity to review draft manuscripts at the time of external peer review. The purpose of such review was to allow input on the clarity of the science presented but not on interpretation of the research findings. The researchers' scientific conclusions and professional judgments were not subject to the funders' control.

Most of the authors (Gentry, Van Landingham, and Mundt) are employees of Ramboll Environ US Corporation, and performed this work as part of their normal employment. Ramboll Environ US Corporation is a consulting firm providing services in environmental and health sciences matters to private firms, trade organizations, and government agencies. Mr. Allen provided senior technical review on the manuscript and its content as an independent consultant with fee for service. The authors had sole responsibility for the analyses performed, the interpretations made, conclusions drawn and the writing of the paper, which may not necessarily reflect the views of RFHEE. None of the authors have appeared as experts in any litigation related to formaldehyde.

Appendix A.. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.yrtph.2016.10.011.

Transparency document

Transparency document related to this article can be found online at http://dx.doi.org/10.1016/j.yrtph.2016.10.011.

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Message

From: Jinot, Jennifer [Jinot.Jennifer@epa.gov]
Sent: 5/17/2016 5:59:11 PM
To: Jinot, Jennifer [Jinot.Jennifer@epa.gov]
Subject: FW: David's comments on cancer d-r
Attachments: DBcmts(ver4) on FormaldehydeTRdraft050616-jj.docx

From: Jinot, Jennifer
Sent: Tuesday, May 17, 2016 1:55 PM
To: Glenn, Barbara <Glenn.Barbara@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: David's comments on cancer d-r

hi, Barbara. here are my revisions in response to David's comments. they start on page 631. he also had comments on Ravi's section, which i didn't look at. if you have any questions, let me know. jj
p.s. i reckon you know that the section and table and page #s are all off in this version. hopefully all's well in your master version.

From: Glenn, Barbara
Sent: Wednesday, May 11, 2016 3:57 PM
To: Jinot, Jennifer <Jinot.Jennifer@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: David's comments on cancer d-r

Hi Jennifer,
In preparation for sending the draft assessment for review by the ERC on May 20th, David has send some comments on the dose-response section, including some on sections of the cancer dose-response section based on the epidemiology data. Could you look at them and make any needed changes?

I've sent the document that he reviewed. In order to get the changes into our working document, if you send this one to Andrew or me with the track changes showing, we will know what parts to paste in.

Thank you, Barbara

Message

From: Jinot, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D0EDF66A00054AFE84F4AB5C5119562F-JINOT, JENNIFER]
Sent: 3/21/2017 3:22:40 PM
To: Samuels, Crystal [Samuels.Crystal@epa.gov]
Subject: FW: FA Ramboll Environ Files
Attachments: New Formaldehyde Science Ramboll Environ_110716_final.pptx; New Formaldehyde Science Ramboll Environ_110716_final.pdf; ACC Formaldehyde Panel - Letter to NIEHS 10 17 16.pdf; NIEHS Response ltr to Dr White 10 19 16.pdf; Van Landingham et al. 2016.pdf

hi, Crystal. i only attended the 7 Nov 2016 ACC meeting, and this is the only email i have about it. jj

From: Shams, Dahnish
Sent: Monday, November 07, 2016 3:34 PM
To: Perovich, Gina <Perovich.Gina@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Jinot, Jennifer <Jinot.Jennifer@epa.gov>; Bateson, Thomas <Bateson.Thomas@epa.gov>; Fritz, Jason <Fritz.Jason@epa.gov>; Soto, Vicki <Soto.Vicki@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>
Subject: FA Ramboll Environ Files

Hi all – Attached to this email is the presentation and the supplemental files from the Ramboll Environ presentation today.

Let me know if you have any questions.

Thanks!

Dahnish

Integrated Risk Information System (IRIS) Program
National Center for Environmental Assessment
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Appointment

From: Glenn, Barbara [Glenn.Barbara@epa.gov]
Sent: 6/21/2016 2:47:44 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]

Subject: Formaldehyde Issues
Attachments: Charge_Peer Review_062116.docx; EXECUTIVE SUMMARY - 10Jun2016DBsuggests.docx
Location: DCRoomPYS11771-Crystal

Start: 6/23/2016 5:00:00 PM
End: 6/23/2016 7:00:00 PM
Show Time As: Busy


Charge_Peer Review_062116....


EXECUTIVE SUMMARY - 10J...

Agenda and attachments

Charge questions
Executive summary
Probabilities

Message

From: Kraft, Andrew [Kraft.Andrew@epa.gov]
Sent: 3/23/2017 1:07:58 PM
To: Samuels, Crystal [Samuels.Crystal@epa.gov]
CC: Birchfield, Norman [Birchfield.Norman@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: RE: FOIA Assignment for EPA-HQ-2017-004634 - Public Meetings with ACC
Attachments: FA Ramboll Environ Files; Meeting today with Ramboll reps; RE: Meeting with Robinan Gentry and Ken Mundt (Ramboll.com); RE: Request for Meeting; RE: Draft reply to ACC on formaldehyde; RE: Draft reply to ACC on formaldehyde; RE: Draft reply to ACC on formaldehyde; Draft reply to ACC on formaldehyde; RE: Meeting with Robinan Gentry and Ken Mundt (Ramboll.com); Request for Meeting; Meeting with Robinan Gentry and Ken Mundt (Ramboll.com); RE: meeting request; FW: meeting request; RE: Lou says the june letter to ACC did go out at that time...; RE: Lou says the june letter to ACC did go out at that time...; Lou says the june letter to ACC did go out at that time...; RE: meeting request; FW: meeting request; RE: MORE RE FW: Letter from the ACC's Formaldehyde Panel to EPA; RE: MORE RE FW: Letter from the ACC's Formaldehyde Panel to EPA; RE: meeting request; FW: meeting request; RE: meeting request; MORE RE FW: Letter from the ACC's Formaldehyde Panel to EPA; FW: Letter from the ACC's Formaldehyde Panel to EPA; FW: Letter from the ACC's Formaldehyde Panel to EPA; Now the actual letter ....FW: Letter from the ACC's Formaldehyde Panel to EPA; FW: Letter from the ACC's Formaldehyde Panel to EPA; RE: meeting request; RE: meeting request; FW: meeting request; RE: meeting request; RE: meeting request; FW: meeting request; RE: meeting request; meeting request

Hi Crystal,

Please find attached all of my emails related to the letter and subsequent meeting with Drs. Gentry and Mundt from Ramboll-Environ. Please let me know if you need any additional information.

Thank you,
Andrew

From: Ross, Mary
Sent: Tuesday, March 21, 2017 11:06 AM
To: Avery, James <Avery.James@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Jinot, Jennifer <Jinot.Jennifer@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Soto, Vicki <Soto.Vicki@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>
Cc: Samuels, Crystal <Samuels.Crystal@epa.gov>; Kadry, Abdel-Razak <Kadry.Abdel@epa.gov>
Subject: RE: FOIA Assignment for EPA-HQ-2017-004634 - Public Meetings with ACC

Hi everyone. Just want to emphasize the need to follow up on this FOIA, and compile the records as soon as possible so that we can finish this one off. Thanks!

From: Avery, James
Sent: Monday, March 20, 2017 3:41 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Jinot, Jennifer <Jinot.Jennifer@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Soto, Vicki <Soto.Vicki@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>

Cc: Samuels, Crystal <Samuels.Crystal@epa.gov>; Kadry, Abdel-Razak <Kadry.Abdel@epa.gov>
Subject: FW: FOIA Assignment for EPA-HQ-2017-004634 - Public Meetings with ACC

Hello All,

NCEA received a new FOIA request below regarding meetings with ACC on Mar 1, 2017 (NCEA and IRIS Leadership), Feb 21, 2017 (Formaldehyde IRIS Assessment) and Nov 7, 2016 (Formaldehyde).

Pat Rizzuto's FOIA is requesting any materials the meeting participants shared with each other during the meeting and emails about each meeting that were exchanged prior to and after it.

Please review your emails to determine if you have any that are responsive to this request and submit any responsive email/materials to Crystal Samuels by COB Thursday, March 23.

Below is a list of the meetings, attendees (NCEA in bold) and materials that are publicly available on the EPA IRIS webpage (so no need to provide those) .

Thanks,

James

James W. Avery, Ph.D.
Deputy Director (acting)
IRIS Division
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (8601-P)
Washington, DC 20460
703-347-8668 (office phone), 202 834-8379 (cell phone)

Event Title:	**NCEA and IRIS Leadership**
Date:	1-Mar-17
Time:	12:10 AM - 12:12 AM
Keywords:	IRIS, Scientific Process
Attendees:	Nancy Beck - American Chemistry Council (ACC) Neeraja Erraguntia - ACC Ann Mason - ACC Liz Bowman - ACC **Tina Bahadori - US, EPA, NCEA** **Lou D'Amico - US, EPA, NCEA** **Kris Thayer - US, EPA, NCEA** **Samantha Jones - US, EPA, NCEA** **James Avery - US, EPA, NCEA** **Mary Ross - US, EPA, NCEA**

Event Title:	**Formaldehyde IRIS Assessment**
Date:	21-Feb-17
Time:	2:00 PM - 3:30 PM

Keywords:	Formaldehyde, NAS Recommendations
Attachments:	NAS Recommendations on Draft Formaldehyde IRIS Assessment (8 pp, 2.5MB)
Attendees:	Robinan Gentry - Environ Ramboll Mark Gruenwald - Hexion, Inc. Kimberly White - American Chemistry Council (ACC) Stewart Holm - American Forest and Paper Association Kenneth Mundt - Environ Ramboll Raj Sharma - Georgia-Pacific Jim Sherman - Celanese **Samantha Jones - US, EPA, NCEA** **Tina Bahadori - US, EPA, NCEA** **Mary Ross - US, EPA, NCEA** **Kris Thayer (P) - US, EPA, NCEA**

Event Title:	**Formaldehyde**
Description:	Request from Drs. Robinan Gentry and Ken Mundt (Ramboll Environ) to meet with members of the IRIS Program and other members of EPA to discuss the recent work they have been conducting for formaldehyde.
Date:	7-Nov-16
Time:	2:00 PM - 3:00 PM
Keywords:	Formaldehyde, American Chemistry Council
Attachments:	Ltr. from ACC to NIEHS (2 pp, 259.4K) NIEHS Response to ACC (1 pp, 179.4K) Slide Presentation - IRIS Tox Review of Formaldehyde (18 pp, 441.3K)
Attendees:	Robinan Gentry - Ramboll Environ Kenneth Mundt - Ramboll Environ **Dahnish Shams - US, EPA, NCEA** **Vincent Cogliano - US, EPA, NCEA** **Michael Slimak - US, EPA, NCEA** **Samantha Jones - US, EPA, NCEA** **Barbara Glenn - US, EPA, NCEA** **Andrew Kraft - US, EPA, NCEA** **Jennifer Jinot - US, EPA, NCEA** **Norman Birchfield - US, EPA, NCEA** **David Bussard - US, EPA, NCEA** **Vicki Soto (P) - US, EPA, NCEA** **Mary Ross (P) - US. EPA, NCEA** **Gina Perovich (P) - US, EPA, NCEA**

From: Samuels, Crystal
Sent: Wednesday, March 15, 2017 3:38 PM
To: Avery, James <Avery.James@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: FW: FOIA Assignment for EPA-HQ-2017-004634

Hello,

Attached below is a new FOIA request assigned to NCEA. Please review to determine if there are records within IRIS related to this request. Please respond to me by March 22, 2017. Please contact me with any questions. Thank you.

From: foia@regulations.gov [mailto:foia@regulations.gov]
Sent: Friday, March 10, 2017 12:57 PM
To: Samuels, Crystal <Samuels.Crystal@epa.gov>
Subject: FOIA Assignment for EPA-HQ-2017-004634

You have been assigned to the FOIA request EPA-HQ-2017-004634. Additional details for this request are as follows:

- Assigned By: Peter Evanko
- Request Tracking Number: EPA-HQ-2017-004634
- Due Date: N/A
- Requester: Pat Rizzuto
- Request Track: Simple
- Short Description: N/A
- Long Description: I would like to request the attendee lists for three meetings members of the public held with staff from the EPA's Integrated Risk Information System, or IRIS, program. I also would like to receive any materials the meeting participants shared with each other during the meeting, and I would like to receive emails about each meeting meeting that were exchanged prior to and after it. The meeting dates and subjects were as follows: Mar 01, 2017: NCEA and IRIS Leadership Feb 21, 2017: Formaldehyde IRIS Assessment Nov 07, 2016: Formaldehyde
- Assigned Comments: IRIS

Message

From: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Sent: 3/23/2017 2:05:16 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: animal d-r section attached
Attachments: Main SCC d-r-03-23-17.docx

Importance: High

--Ravi.

Ravi Subramaniam, PhD / Chief, Toxic Effects Branch-IRIS, NCEA-ORD, EPA.
Room PYS-11782/ **Ph: (703) 347-8606 (o); (571) 305-3601 (m)**

Message

From: D'Amico, Louis [DAmico.Louis@epa.gov]
Sent: 2/1/2017 4:01:49 PM
To: Bussard, David [Bussard.David@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: RE: FA and ACC
Attachments: ACC FA Response -BurkeKadeli_final.docx; ACC_Letter_on_NAS_Recommendations_for_Formaldehyde_-_Final_04_13_16 (1).pdf

I don't have the signed burke Kadeli response (at least as I could find from home). Is this the one you're talking about?

Louis D'Amico, Ph.D.
Assistant Center Director for Communications and Regulatory Support (Acting)
U.S. EPA, ORD/NCEA
damico.louis@epa.gov
O: (703) 347-0344 M: (703) 859-1719

-----Original Message-----
From: Bussard, David
Sent: Wednesday, February 01, 2017 9:53 AM
To: Birchfield, Norman <Birchfield.Norman@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: FA and ACC

I can't find final letter to ACC re stopping rule dates. I have a draft from around May 2016. Anyone have the final?

David Bussard
Sent from my iPhone

April 13, 2016

Dr. Thomas Burke
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Mail code: 8101R
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Mr. Lek Kadeli
Principal Deputy Assistant Administrator for Management
Office of Research and Development
U.S. Environmental Protection Agency
Mail code: 8101R
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Dear Dr. Burke and Mr. Kadeli:

In the four years since the National Academy of Sciences (NAS) called for improving the scientific quality of the EPA's Integrated Risk Information System (IRIS) program, generally, and the draft IRIS Toxicological Review of Formaldehyde, specifically, we have seen little in the way of full implementation of many of those recommendations.[1] As key stakeholders, this is very frustrating. The NAS requested improvements to the overall process and approaches utilized by the entire IRIS program to evaluate scientific data and determine human health hazards. Notably, the NAS also found that EPA's assessment of formaldehyde was not consistently developed, did not sufficiently document methods to identify or evaluate relevant scientific studies, and did not integrate the lines of evidence from the available animal, human, and mechanistic data. The NAS also called EPA's formaldehyde IRIS assessment subjective and potentially problematic given the inconsistencies in the available scientific data.

Although the Agency has offered assurances to Congress that the critically needed reforms of the IRIS program are underway, we are concerned with the lack of transparency as to whether or how EPA has addressed the numerous scientific recommendations for the draft formaldehyde IRIS assessment. To date, it is still unclear what changes, if any, have been completed that should result in significant improvements to the scientific quality of IRIS assessments, in general, as well as those specific improvements that must be made to the formaldehyde assessment. Given that there has been a significant amount of formaldehyde science generated over the past several years that directly addresses the NAS recommendations, it is particularly essential that the Agency demonstrate how it has systematically evaluated and integrated the different lines of scientific evidence in a revised formaldehyde IRIS assessment.

Formaldehyde occurs naturally in living cells, and is exhaled in human breath. It also is one of the most common and extensively studied compounds in commerce. It is produced and used in the manufacture of a variety of commercial, consumer, and industrial products. Given that the 2011 NAS report identified

[1] National Academy of Sciences (NAS). National Research Council (NRC). 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. Board of Environmental Studies and Toxicology. Division of Earth and Life Sciences.

significant concerns with the EPA's draft IRIS assessment of formaldehyde, the continued credibility of the IRIS program depends on a scientifically defensible assessment developed through a fully transparent process. We are deeply concerned that a less than robust assessment could propagate unwarranted concern by the public, prompt regulatory actions that do not benefit public health, and unjustifiably disrupt commerce.

It is particularly essential that the scientific basis for the formaldehyde IRIS assessment be able to stand up to the full breadth of scientific scrutiny and critique. The revised assessment must fully and transparently implement all of the recommendations identified by the NAS for the IRIS program. Further, the revised assessment must also fully incorporate the formaldehyde specific NAS recommendations and be based on a comprehensive review of all the newly published science.

Again, we request a full update on the status of the IRIS Toxicological Review of Formaldehyde, including answers to the following key questions.

1. Is EPA still considering newly published scientific studies and evaluations for inclusion in the revised formaldehyde IRIS assessment?

    a. If so, up to what date will EPA accept newly published data for inclusion in the revised formaldehyde IRIS assessment?
    b. If not, what criteria will EPA use to determine if a new study is a "game changer" and should be evaluated for inclusion in the revised formaldehyde IRIS assessment?

2. Given that the science around formaldehyde is complex and diverse, what type of framework is the Agency using to integrate the epidemiology, toxicology and mechanistic data? What steps is EPA taking, specifically in the formaldehyde IRIS assessment, to ensure integration of the scientific literature to avoid over-reliance on any one study?

3. In 2014, EPA hosted a scientific workshop on the epidemiology studies that are relevant to the formaldehyde IRIS assessment. At that time, the Agency expressed a commitment to hold a second epidemiology workshop. Considering the significant divergent interpretations of the findings of the available formaldehyde epidemiology studies, why has EPA not conducted a second workshop? Why can't such a workshop be convened before the revised draft formaldehyde IRIS assessment is released?

4. Recognizing that many epidemiology studies are conducted on foreign populations with different work environments, dietary and nutrition habits, etc., please explain how the Agency extrapolates or adjusts those study findings to make them relevant to U.S. populations.

5. Scientists, including the National Institutes of Health (NIH) Director Francis Collins[2], are increasingly calling for replication of study findings, particularly in those instances where the findings are novel. Under what circumstances, if at all, will EPA base the establishment of risk

[2] Collins, Francis S., and Lawrence A. Tabak. "NIH plans to enhance reproducibility." Nature 505.7485 (2014): 612.

values in IRIS assessments, in whole or in part, on studies whose findings have not been replicated?

6. What 2011 and 2014[3] NAS recommendations are being applied to the revised formaldehyde IRIS assessment?

   a. When EPA is evaluating the available scientific data, what criteria is the Agency using in determining the quality and limitations of the key studies? What methods are being used to weigh, synthesize and integrate evidence to scientifically substantiate any conclusions it may draw about formaldehyde toxicity and carcinogenicity (especially leukemogenicity)?
   b. EPA has committed to the application of tools such as systematic review to identify studies to be evaluated in an IRIS assessment. While the currently available tools may help ensure the inclusion of studies, they may not address the quality of those studies. Recognizing the NAS has called for the establishment of study quality criteria, what steps has EPA taken to address that recommended reform and how will this be implemented in the revised formaldehyde IRIS assessment?

7. What steps remain in the peer review process for the revised formaldehyde IRIS assessment? Does EPA plan to submit the revised IRIS assessment to peer review by the Chemical Assessment Advisory Committee? In light of the previous engagement by the NAS and in the interests of closure with the NAS recommendations, is EPA considering asking the Academy to be the peer review body for the revised formaldehyde IRIS assessment?

Formaldehyde is one of the most commonly used building block chemicals, utilized in numerous applications. Given that the 2011 NAS report was critical of the 2010 draft IRIS Toxicological Review of Formaldehyde, we again submit it is essential that EPA take the necessary time to implement the corrective measures to ensure a scientifically sound and defensible product.

Sincerely,

Kimberly Wise White, PhD
American Chemistry Council (ACC)
Senior Director
Chemical Products & Technology Division

cc to Dr. Ken Olden and Dr. Vince Cogliano

[3] National Academy of Sciences (NAS). NRC (National Research Council). 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Board of Environmental Studies and Toxicology. Division of Earth and Life Sciences. Available at http://www.nap.edu/catalog.php?record_id=18764.

Message

From: Lidka Maslankiewicz [lidka.maslankiewicz@rivm.nl]
Sent: 8/29/2017 11:59:20 AM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]
CC: Els Smit [els.smit@rivm.nl]; Paul Janssen [paul.janssen@rivm.nl]; Joke Herremans [joke.herremans@rivm.nl]
Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,

My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.

We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response" (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

Kind regards

Lidka

Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
www.rivm.nl *De zorg voor morgen* begint vandaag

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www.rivm.nl/en Committed to *health and sustainability*

Message

From: Bussard, David [Bussard.David@epa.gov]
Sent: 8/19/2015 9:06:06 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Sonawane, Bob [Sonawane.Bob@epa.gov]
Subject: FA specific comments
Attachments: FormaldehydeTRdraft072315 DBcmts.docx

Having read the Preamble, Exec Summary and some of the Hazard ID, it seems to me I should go ahead and pass on some of the detailed comments I have, and then we should go over whether after considering those we should send this to others to review this portion, or wait for the quantification.

I am thinking that I would not send it the ERC until we have the full document. I know I am finding it hard to know where to focus my energy on such a large piece of work. But, perhaps you can think of how to focus review.

Also, remind me when we'll have a draft Response to Comments.

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 9/14/2016 12:39:07 PM
To: Birchfield, Norman [Birchfield.Norman@epa.gov]
Subject: FW: IRIS assessment for formaldehyde
Attachments: Formaldehyde and Paraformaldehyde PWP 9-14-16.docx

From: ONeill, Sandra
Sent: Wednesday, September 14, 2016 8:33 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>
Cc: Gayoso, Jose <Gayoso.Jose@epa.gov>
Subject: FW: IRIS assessment for formaldehyde

Andrew, et al.,

AD is nearing completion of the Formaldehyde and Paraformaldehyde Preliminary Work Plan. Our goal is to complete this workplan by the end of next week. We mention that we will include the IRIS review and determine whether new endpoints would be selected, incorporating this into our registration review. I've attached a draft of the document, can you let me know if you have any comments by next Tuesday, March 20? And also, if you have any questions on the document.

Thanks in advance.

Sincerely,

Sandra O'Neill
Chemical Review Manager
OCSPP/OPP/AD
703 347 0141

From: Kraft, Andrew
Sent: Tuesday, August 16, 2016 4:39 PM
To: ONeill, Sandra <ONeill.Sandra@epa.gov>
Cc: McMahon, Tim <McMahon.Tim@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: RE: IRIS assessment for formaldehyde

Hi Sandra,

Yes, Barbara and I are working on the IRIS formaldehyde assessment (we are the assessment managers). We do not currently have a publically available, up-to-date schedule for release of the document for peer review, nor for finalization after peer review. Thus, we do not have a date that could be released through your workplan.

Note that prior to release of the assessment for peer review (which can take up to several years to complete, depending on the peer review mechanism), we still have to complete internal EPA clearance of the document, Interagency review by federal partners, and release of the assessment for comments from the general public.

Barbara, myself, and/ or Norm (our branch chief) can address any questions you may have, and, internally, we can provide you with more details on the assessment's progress.

Best,
Andrew

From: ONeill, Sandra
Sent: Tuesday, August 16, 2016 3:38 PM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: McMahon, Tim <McMahon.Tim@epa.gov>
Subject: IRIS assessment for formaldehyde

Hi Andrew,

I'm AD's CRM working on the formaldehyde and paraformaldehyde registration review case. We're publishing a Preliminary Work Plan for this case by the end of September and also providing a brief presentation to OPP's front office at the end of this month on this case. I understand you're working on the IRIS assessment? Do you have a timeline in place for when the peer review might be completed, or know who I might contact for this information?

Thanks very much,

Sandra O'Neill
Chemical Review Manager
Regulatory Management Branch 2 II Antimicrobials Division II OPP/OCSPP II U.S. EPA II (703) 347-0141

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 3/23/2017 3:00:35 PM
To: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Subject: RE: animal d-r section attached
Attachments: Main SCC d-r-03-23-17ak.docx

From: Subramaniam, Ravi
Sent: Thursday, March 23, 2017 10:05 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: animal d-r section attached
Importance: High

--Ravi.

Ravi Subramaniam, PhD / Chief, Toxic Effects Branch-IRIS, NCEA-ORD, EPA.
Room PYS-11782/ **Ph: (703) 347-8606 (o); (571) 305-3601 (m)**

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 4/19/2016 9:08:34 PM
To: Gibbons, Catherine [gibbons.catherine@epa.gov]
Attachments: FormaldehydeAppendixdraft_040716.docx; FormaldehydeTRdraft031016.docx

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 12/21/2017 10:17:47 PM
To: Cote, Ila [Cote.Ila@epa.gov]
CC: Bahadori, Tina [Bahadori.Tina@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Bussard, David [bussard.david@epa.gov]; Ramasamy, Santhini [Ramasamy.Santhini@epa.gov]
Subject: Formaldehyde review, Part 2 (Main draft, aka Toxicological Review)
Attachments: Formaldehyde Main Text 122117CLEAN.docx

☺

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 1/7/2016 10:06:05 PM
To: Whalan, John [whalan.john@epa.gov]
Subject: TR draft
Attachments: FormaldehydeTRdraft12215.docx

Hi John,

I know you just asked for Jason's section, but I thought it might be useful for you to have a recent copy of the compiled draft.

Please see the attached.

Have a great weekend,
Andrew

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 2/1/2017 4:06:36 PM
To: D'Amico, Louis [damico.louis@epa.gov]
Subject: FW: can you please send that letter? thanks.
Attachments: ACC FA Response -BurkeKadeli_final.docx

… but I didn't cc you, lol

From: Kraft, Andrew
Sent: Wednesday, February 01, 2017 10:15 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Subject: FW: can you please send that letter? thanks.

From: Kraft, Andrew
Sent: Wednesday, February 01, 2017 10:14 AM
To: Bussard, David <bussard.david@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>
Cc: Glenn, Barbara <glenn.barbara@epa.gov>
Subject: FW: can you please send that letter? thanks.

This one?

From: D'Amico, Louis
Sent: Wednesday, October 19, 2016 1:21 PM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>
Subject: RE: can you please send that letter? thanks.

This may be helpful context before tomorrow's discussion on the latest ACC letter on FA to mike. It's a copy of the response sent from Tom and Lek to ACC's previous shot across the bow.

-Lou

Louis D'Amico, Ph.D.
Acting Communications Director, ORD/NCEA
damico.louis@epa.gov
O: (703) 347-0344 M: (703) 859-1719

From: Kraft, Andrew
Sent: Wednesday, October 19, 2016 1:14 PM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: can you please send that letter? thanks.

Message

From: Shams, Dahnish [Shams.Dahnish@epa.gov]
Sent: 2/21/2017 7:08:16 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]
Subject: Fwd:
Attachments: image2017-02-21-140137.pdf; ATT00001.htm

FYI -

Integrated Risk Information System (IRIS) Program
National Center for Environmental Assessment
Office of Research and Development, U.S. EPA
O: (703) 347-0167

Begin forwarded message:

> **From:** "VA-PYS-11251-M@epa.gov" <VA-PYS-11251-M@epa.gov>
> **To:** "Shams, Dahnish" <Shams.Dahnish@epa.gov>

Message

From: Kraft, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4A94A4F199B247778ABB02285A51B927-KRAFT, ANDREW]
Sent: 6/2/2017 10:06:17 PM
To: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Subject: Re: overview
Attachments: formaldehyde_assessment overview_052217teamreview060217.docx

Sorry! I must have sent before it finished loading.

From: Subramaniam, Ravi
Sent: Friday, June 2, 2017 5:08 PM
To: Kraft, Andrew
Subject: RE: overview

Hey Andrew

This email had no attachment in it!

--Ravi.

Ravi Subramaniam, PhD / Chief, Toxic Effects Branch-IRIS, NCEA-ORD, EPA.
Room PYS-11782/ **Ph: (703) 347-8606 (o); (571) 305-3601 (m)**

From: Kraft, Andrew
Sent: Friday, June 02, 2017 3:45 PM
To: Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>
Cc: Glenn, Barbara <Glenn.Barbara@epa.gov>
Subject: overview

Hi Ravi,

Please use this version- you are the only team member still working in this document, so feel free to work with it offline. Please send it back by COB Monday or first thing in the morning on Tues. thanks!

-Andrew

Message

From: Cogliano, Vincent [cogliano.vincent@epa.gov]
Sent: 4/19/2016 2:14:50 PM
To: Olden, Kenneth [Olden.Kenneth@epa.gov]; Ross, Mary [Ross.Mary@epa.gov]; Perovich, Gina [Perovich.Gina@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Walsh, Debra [Walsh.Debra@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Hagerthey, Scot [Hagerthey.Scot@epa.gov]; Gatchett, Annette [Gatchett.Annette@epa.gov]; Johnson, Craig [Johnson.Craig@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]
CC: Rieth, Susan [Rieth.Susan@epa.gov]; Hotchkiss, Andrew [Hotchkiss.Andrew@epa.gov]; Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]
Subject: FW: IRIS and formaldehyde, part 2
Attachments: ACC Draft Letter on NAS Recommendations for Formaldehyde - Final 04 13 16.pdf

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]
Sent: Friday, April 15, 2016 3:27 PM
To: Burke, Thomas <Burke.Thomas@epa.gov>; Kadeli, Lek <Kadeli.Lek@epa.gov>
Cc: Olden, Kenneth <Olden.Kenneth@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>
Subject: Letter Regarding Implementation of NAS Recommendations for IRIS

Dear Dr. Burke and Mr. Kadeli:

Please find attached a letter regarding implementation of the National Academy of Sciences recommendations for IRIS.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council
Senior Director, Chemical Products & Technology Division
Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
O: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

Message

From: Subramaniam, Ravi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E738F9D27062486E9047184B867FD968-SUBRAMANIAM, RAVI]
Sent: 5/25/2016 5:10:36 PM
To: Enchill, Kobina [enchill.kobina@epa.gov]
Subject: file 1
Attachments: Formaldehyde_draft Tox Review_ERC_May2016.docx

Kobina

Thanks for being available at short notice. Here is the document. Note I want you to do this only for stuff between pages R-678 to R-708. (The same problem exists for material on other pages but we are not going to bother with those.)

--Ravi.

Ravi Subramaniam, PhD / Chief (acting), Toxic Effects Branch-IRIS, NCEA-ORD, EPA.
Room PYS-11782/ **Ph: (703) 347-8606**

Message

From: Vulimiri, Suryanarayana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1A4F972302434EC6A04B015B14845A9D-VULIMIRI, SURYANARAYANA]
Sent: 11/22/2017 1:26:56 PM
To: Bateson, Thomas [Bateson.Thomas@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Jason Fritz [fritz.jason@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Makris, Susan [Makris.Susan@epa.gov]; Segal, Deborah [Segal.Deborah@epa.gov]; Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Whalan, John [Whalan.John@epa.gov]
CC: Ramasamy, Santhini [Ramasamy.Santhini@epa.gov]; Bussard, David [Bussard.David@epa.gov]
Subject: Hot off the press - on formaldehyde
Attachments: Mundt et al 2017_Eupub.pdf

Mundt et al 2017_Eupub.pdf

1. Regul Toxicol Pharmacol. 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

Mundt KA[1], Gentry PR[2], Dell LD[2], Rodricks JV[2], Boffetta P[3].

Author information:

1 Environment and Health, Ramboll Environ US Corporation, Amherst, MA, USA. Electronic address: kmundt@ramboll.com.

2 Environment and Health, Ramboll Environ US Corporation, Amherst, MA, USA.

3 Icahn School of Medicine at Mount Sinai, New York, USA.

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehyde causes leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRIS review and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC

recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

Sury Vulimiri, Ph.D., DABT National Center for Environmental Assessment, Office of Research & Development, US EPA. Phone: 919-541-3558 | Fax: 919-541-0245 | vulimiri.sury@epa.gov

Message

From: My NCBI [efback@ncbi.nlm.nih.gov]
Sent: 11/22/2017 11:37:26 AM
To: Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]
Subject: What's new for 'formaldehyde' in PubMed

This message contains My NCBI what's new results from the National Center for Biotechnology Information (NCBI) at the U.S. National Library of Medicine (NLM).
Do not reply directly to this message.

Sender's message: Formaldehyde alerts for Sury:

Sent on Wednesday, 2017 November 22
Search: **formaldehyde**

View complete results in PubMed (results may change over time).

Edit saved search settings, or unsubscribe from these e-mail updates.

PubMed Results

Item 1 of 1

1. Regul Toxicol Pharmacol. 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

Mundt KA[1], Gentry PR[2], Dell LD[2], Rodricks JV[2], Boffetta P[3].

Author information:

1 Environment and Health, Ramboll Environ US Corporation, Amherst, MA, USA. Electronic address: kmundt@ramboll.com.

2 Environment and Health, Ramboll Environ US Corporation, Amherst, MA, USA.

3 Icahn School of Medicine at Mount Sinai, New York, USA.

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehyde causes leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRIS review and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

PMID: 29158043

Message

From: Whalan, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB12B5D4BD5E4BD88CCDE4F514C56A8E-WHALAN, JOHN]
Sent: 12/15/2016 1:45:10 PM
To: Bussard, David [Bussard.David@epa.gov]
Subject: RE: sprint materials
Attachments: A Brief Bulleted History of FA assessment JW 7-11-14.docx; Brief History for GAO 2-18-11 w DB changes.final.docx

David,

Attached are 2 brief histories for FA that may be useful to you. Andrew and Barbara are your best source for information from 2011 to present.

John

From: Bussard, David
Sent: Wednesday, December 14, 2016 4:21 PM
To: Whalan, John <Whalan.John@epa.gov>
Subject: FW: sprint materials

John,

I know at times I have tried to compile a history of steps along the way on formaldehyde.

Do you have something on that?

David

From: Fritz, Jason
Sent: Wednesday, December 14, 2016 4:13 PM
To: Bussard, David <Bussard.David@epa.gov>
Subject: RE: sprint materials

Cool! Yeah, I figured that the information was available if we sought out the right people and gave them the opportunity to assemble it.
Thank you!
Jason

From: Bussard, David
Sent: Wednesday, December 14, 2016 4:03 PM
To: Fritz, Jason <Fritz.Jason@epa.gov>
Subject: sprint materials

An aside, if it was worth it, we could reconstruct a detailed schedule for formaldehyde.
John Whalan likely has much of the info for a good portion of the timeline.

David A Bussard
Director, Washington Division
National Center for Environmental Assessment, NCEA
ORD, USEPA